



# "Anslingerian" Politics: The History of Anti-Marijuana Sentiment in Federal law and How Harry Anslinger's Anti-Marijuana Politics Continue to Prevent the FDA and other Medical Experts from Studying Marijuana's Medical Utility

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**“Anslingerian” Politics:  
The History of Anti-Marijuana Sentiment in Federal Law and How Harry Anslinger’s  
Anti-Marijuana Politics Continue to Prevent the FDA and Other Medical Experts from  
Studying Marijuana’s Medical Utility.**

**Jesse J. Ransom  
Harvard Law School  
Written Work Requirement.  
Final Paper for  
Food and Drug Law.  
Professor Peter Barton Hutt.  
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**TABLE OF CONTENTS**

GENERAL INTRODUCTION.....	
CHAPTER 1.....	
INTRODUCTION.....	
A.	
INDUSTRIAL USE.....	
MEDICAL USE.....	
RECREATIONAL USE.....	

B.

C.

CHAPTER 2.....

INTRODUCTION.....

A.

STAGE 1---PRECLINICAL INVESTIGATION IN PREPARATION

OF THE IND APPLICATION.....

STAGE 2—THE 3-PHASE HUMAN INVESTIGATION PROCESS.....64

STAGE 3---SUBMISSION AND FDA EXAMINATION OF THE

NDA.....

B.

MEDICINAL MARIJUANA.....

OBSTACLES TO FEDERAL LEGALIZATION OF MEDICINAL  
MARIJUANA INHERENT IN THE NATURE OF MARIJUANA.....79

OBSTACLES TO FEDERAL LEGALIZATION OF MEDICINAL  
MARIJUANA CREATED BY FEDERAL DRUG ENFORCEMENT  
OFFICIALS.....

CONCLUSION.....	
BIBLIOGRAPHY.....	

## GENERAL INTRODUCTION

The American federal government vehemently resists the notion that marijuana has any potential therapeutic utility for the past five decades, and yet it unofficially continues to supply marijuana for therapeutic uses to a few medical patients under a government program.<sup>1</sup> For the past 29 years, marijuana has resided under the federal controlled substance classification reserved for chemical substances that serve no medical purpose.<sup>2</sup> Yet, during the same time that the federal government has defended this restrictive classification it has quietly recognized marijuana's medical potential by approving the use of synthesized drugs containing many of marijuana's active ingredients.<sup>3</sup>

Few governmental issues have elicited more schizophrenic, inconsistent, or seemingly illogical responses from the federal government than the issue of medical marijuana (also known as hemp in the industrial arena and cannabis in the medical arena).<sup>4</sup> The highly-politically-charged symbolism with which marijuana has been associated for most of the twentieth century has had a dramatic effect on the federal government's approach to the medical marijuana issue ever

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<sup>1</sup>See Lester Grinspoon, M.D. & James B. Bakalar, *Marihuana, the Forbidden Medicine* 22 (1997).

<sup>2</sup>See *id.* at 13.

<sup>3</sup>See Allison L. Bergstrom, *Medical Use of Marijuana: A Look at Federal & State Responses to California's [sic] Compassionate Use Act*, 2 *DePaul J. Health Care L.* 155, 163 (Fall, 1997).

<sup>4</sup>See Jack Herer, *Hemp & the Marijuana Conspiracy: The Emperor Wears No Clothes* 1 (Chris Conrad et al. eds., 1995).

since the first federal marijuana legislation was passed in 1937.<sup>5</sup> This paper is intended to demonstrate how the Federal Bureau of Narcotics's propagation of negative images associating marijuana with the anti-social behavior of marginal socio-economic groups in the 1930's still influences the federal government's marijuana policies today. This paper traces the history of marijuana's legal, from its legal status America's infancy, where many colonies considered marijuana such a valuable industrial and medical resource that some actually mandated its cultivation<sup>6</sup>, to its present-day status as an illicit substance that is rarely used in the industrial arena and has no officially recognized medical utility under federal law.

Chapter 1 discusses the 'pre-Anslinger' history of marijuana in America, examining the many industrial and medical purposes for which it was used before the onslaught of the anti-marijuana propaganda campaign waged by the Harry Anslinger and the Federal Bureau of Narcotics in the 1930's and 1940's. It also examines the ways in which the Bureau propagated an image of marijuana as a psychosis-causing recreational drug used by socially marginal classes and racial groups to tap into the most elitist and racist sensibilities of the non-marginal public and gain emotion-based support for a de facto ban on marijuana for any purpose despite the initial objections of medical experts. Finally, it discusses the ways that the influence of this 'Anslingerian' image of marijuana as the 'killer weed' that federal drug enforcement agencies propagated in the 1930's continues to manifest itself in federal drug enforcement agencies' refusal to allow marijuana's medical potential to even be explored by medical agencies such as the Food and Drug Administration even today.

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<sup>5</sup>See Gregg A. Bilz, The Medical Use of Marijuana: The Politics of Medicine, 13 *Hamline J. Pub. L. & Pol'y* 117, 120 (Spring, 1992).

<sup>6</sup>See Herer, supra note 4, at 1.

Chapter 2 focuses more closely on the issues facing supporters of medical marijuana under federal law as it stands today. It also examines more closely the role that the Food and Drug Administration currently plays in determining the medical potential of marijuana, and the reasons that the FDA's role is more limited with respect to marijuana than it would be with other prospective new drugs. Section A discusses the procedures that any group wishing to sponsor a study of marijuana's medical utility must follow before the DEA will even allow them to conduct such a study. It also outlines the rigorous process that this sponsor must follow after obtaining DEA permission to study marijuana if it wishes to obtain the approval of the Food and Drug Administration to market marijuana for therapeutic use. Section B discusses the problems that marijuana would have meeting these procedural requirements under current law, and in terms of the problems marijuana would have meeting the Food and Drug Administration's new-drug-approval requirements in terms of the problems facing anyone attempting to get the DEA to delegate any decision-making authority on this issue to the Food and Drug Administration in the first place. It argues that although marijuana may or may not meet the Food and Drug Administration's standards for acceptability as a medical drug, the DEA's policies continue to prevent the FDA or any other medical organization from ever even getting the opportunity to examine marijuana's utility. The DEA's "'Anslingerian'" marijuana classifications have usurped the Food and Drug Administration's general authority to determine a drug's medical utility in the case of marijuana just as the Federal Bureau of Narcotics usurped the American Medical Association's authority to do so in the 1930's. Moreover, the DEA's "'Anslingerian'" anti-marijuana stance continues to prevent an empirical examination of marijuana's therapeutic potential by medical experts to this day. The paper does not discuss the recent battles between the federal government and several states sparked by the recent attempts of states to circumvent federal marijuana prohibitions by passing

referenda legalizing medical marijuana under state law. Although the federal responses to the state medical marijuana legalization also tend to be heavily influenced by the “Anslingerian” politics of the early twentieth century, the issues raised by each state’s particular laws on the issue are distinct. Consequently, each particular state battle has had its own unique history that demands a far more detailed discussion than this paper can provide. Furthermore, the battle between the states and the federal government encompasses many constitutional issues concerning federalism and the rights of the states that are largely beyond the scope of this paper.

Instead, this paper focuses purely on the issue facing those seeking to gain medical marijuana’s legal acceptance under federal law. It examines the problems that federal drug enforcement agencies have had with marijuana from the era of the Marijuana Tax Act through the recent federal rescheduling litigation, and discusses how the same “Anslingerian” politics that drove anti-drug authorities to remove marijuana from the jurisdiction of medical authorities in the 1930’s have driven current anti-drug authorities to keep the medical marijuana issue out of the jurisdiction of the FDA and other medical organizations to this day.

# Chapter One

## INTRODUCTION

Marijuana's current status under federal law, when viewed amidst all the negative symbolism that has been associated with marijuana throughout much of the twentieth century, might lead one to believe that marijuana has always held a somewhat demonic status in American society. A closer examination of marijuana's history in America, however, indicates that before the 1930's the marijuana plant actually held a status in America quite different than the "chemical-pariah" status with which it is branded today. Up until the 1930's, the medical community regarded marijuana not as a chemical menace, but as a valuable therapeutic tool useful in the treatment of a wide variety of medical maladies. Likewise, the industrial applications for the marijuana plant have proven so numerous and so varied throughout much of American history that as recently as 1938 industrial hemp was hailed as America's newest billion-dollar industry.<sup>7</sup> Marijuana's current status as a chemical pariah under federal law as well as in the public's eyes did not begin to emerge significantly until Harry Anslinger took over the Federal Bureau of Narcotics and began to wage a war against marijuana aimed at outlawing its use in the federal statutes and demonizing it in the public's eyes.<sup>8</sup> This chapter will examine marijuana's history in America, tracing marijuana's legal and social status from America's infancy, where it was considered a valuable industrial and medical commodity, to the present, where federal law reflects

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<sup>7</sup>See Marty Bergoffen & Roger Lee Clark, Hemp as an Alternative to Wood Fiber in Oregon, 11 J. Envtl. L. & Litig. 119, 121-122 (1996).

<sup>8</sup>See Herer, supra note 4, at 24.



a view of marijuana as a chemical menace serving no possible purpose other than the creation of social ills.

Section A discusses marijuana's history before the 1930's, during which time it enjoyed a favorable legal status, and actually served a wide variety of industrial and medical purposes in American society. Section B discusses the highly politically-charged anti-marijuana campaign waged by the Federal Bureau of Narcotics under the direction of Harry Anslinger that brought about the downfall of marijuana's legal and social status in the 1930's in spite of marijuana's many socially beneficial applications. Finally, Section C illustrates the ways in which the same negative symbolism and anti-marijuana propaganda that Harry Anslinger used to push the first federal anti-marijuana legislation through Congress in 1937 has been used by current federal drug enforcement authorities to justify their refusal to allow federal law to reflect marijuana's medical utility even as other federal programs unofficially do so.

A.



may have come from Asia as many as 10,000 years ago during the migration across the Bering Strait.<sup>12</sup> One of the first reports of hemp in the New World came from John De Verrazano, who discovered it in what is now Virginia growing wild in 1524.<sup>13</sup> Since the clothing made from hemp was very sturdy and long-lasting and it grew well without requiring as much care (flourishing without pesticides),<sup>14</sup> Spanish and English settlers grew hemp as a major source of fiber and seed from the sixteenth century well on into the nineteenth century.<sup>15</sup> Interestingly, hemp was actually considered such an important crop that some of the first laws regarding the Marijuana plant were actually “must-grow” laws that required colonial farmers to grow a certain amount of hemp when they farmed, lest they face criminal sanctions.<sup>16</sup> The hemp plant was even made acceptable as legal tender in some colonies in order to encourage its growth.<sup>17</sup> A humorous illustration of the drastically different attitudes that the colonists held toward the hemp plant’s value in colonial times as compared to the prevailing attitudes of today is the fact that drafts of the American Declaration of Independence were written on paper made from hemp.<sup>18</sup> It must seem ironic to the many opponents of the marijuana plant that many believe could contribute significantly to the downfall of American society that the plant actually played a significant role in America’s birth!

Hemp continued to be a major source of fiber for paper and textiles in America through much

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**America** 21 (1983).

<sup>12</sup>See Bergoffen & Clark, supra note 7, at 120-121.

<sup>13</sup>See id. at 121.

<sup>14</sup>See **Ed Rosenthal & Steve Kubby, Why Marijuana Should Be Legal** 59 (1996).

<sup>15</sup>See Himmelstein, supra note 11 at 2.

<sup>16</sup>See Bergoffen & Clark, supra note 7, at 121.

<sup>17</sup>See Herer, supra note 4, at 1.

<sup>18</sup>See Bergstrom, supra note 3, at 158.

of the 1800's.<sup>19</sup> However, in the late 1800's, hemp production in the United States dropped off somewhat.<sup>20</sup> The end of slavery following the Civil War made hemp a more difficult and expensive crop to grow and process, because of the labor-intensive nature of stripping the hemp fibers for conversion into paper and textile products.<sup>21</sup> It became cheaper to import hemp cloth and hemp products from other countries, and hemp farming as a big cash crop fell off in the United States.<sup>22</sup> Still, it was widely recognized that if technology yielded a machine or procedure by which the hemp could be harvested and stripped more cheaply and labor-extensively, hemp would again become a prominent industry in the United States.<sup>23</sup> In fact, even during the hearings concerning the Marihuana Tax Act of 1937<sup>24</sup>, some of the biggest opponents to the Act's passage were manufacturers of hemprope, hempseed, and hempoil, who were concerned about the impact the act would have on their economic interests.<sup>25</sup>

Unfortunately for these manufacturers, however, the Marihuana Tax Act of 1937 was passed<sup>26</sup>, putting a tax on hemp dealing that hemp in the United States a prohibitively expensive and bureaucratically time-consuming crop to grow<sup>27</sup>. Consequently, despite the claims of a 1938 Popular Mechanics article that the invention of hemp harvesting and stripping technology would make hemp "the new billion dollar industry" in America,<sup>28</sup> the obstacles that the Marihuana Tax Act placed in the way of the growth of the hemp industry effectively eliminated the legal

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<sup>19</sup>See Bergoffen & Clark, supra note 7, at 121.

<sup>20</sup>See Himmelstein, supra note 11 at 21.

<sup>21</sup>See Bergoffen & Clark, supra note 7, at 121.

<sup>22</sup>See Himmelstein, supra note 11 at 21.

<sup>23</sup>See Bergoffen & Clark, supra note 7, at 121.

<sup>24</sup>See Bergstrom, supra note 3, at 158 (discussed in greater detail infra Chapter 1, Section B).

<sup>25</sup>See Himmelstein, supra note 11, at 70.

<sup>26</sup>The Marihuana Tax Act was passed, at least in part, due to pressure from other industries (such as the cotton, timber, and chemical industries) who competed with the hemp industry in the arena of textile and paper manufacturing. See Bergstrom, supra note 3, at 158.

<sup>27</sup>See id.

<sup>28</sup>Bergoffen & Clark, supra note 7, at 121-122.

sales of hemp.<sup>29</sup>

The Marihuana Tax Act, in combination with a long line of other U.S. legislative actions, has heavily influenced economic, social, and environmental values all over the world, resulting in severe decreases in worldwide hemp harvesting.<sup>30</sup> In spite of the effect that U.S. attitudes toward marijuana has had on worldwide hemp production, however, hemp continues to be a major source of industrial materials in other parts of the world that have not been so heavily influenced in the twentieth century by U.S. sensibilities. In China, for example, where the growth in the population has necessitated maximal use of renewable resources, hemp continues to be a major source of both cloth and paper.<sup>31</sup> Likewise, in countries that had been allied with the Communist Eastern block, such as Poland, Hungary, and the Ukraine, have grown hemp for its utility as cloth fiber for years.<sup>32</sup> Still, the long-term effect of the Marihuana Tax Act has been to severely curtail the industrial use of hemp in America since the late 1930's.

#### MEDICAL USE

At least as extensive as marijuana's pre-1937 history as an industrial crop is marijuana's history as an oft prescribed medicinal agent, both in the United States, and abroad. Until the passage of the Marihuana Tax Act's passage in 1937,<sup>33</sup> U.S. doctors had as many as 28 different prescriptions containing cannabis that they used to treat various ailments.<sup>34</sup> The history

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<sup>29</sup>The Marihuana Tax Act was modeled after legislation aimed at machine guns. It "required a tax stamp on all sales of hemp products. Also like machine guns, the Federal government refused to issue such stamps, effectively eliminating legal sales of hemp." Bergoffen & Clark, supra note 7, at 122.

<sup>30</sup>See id. at 123.

<sup>31</sup>See id.

<sup>32</sup>See id.

<sup>33</sup>See Bergstrom, supra note 3, at 158 (discussed in greater detail infra Chapter 1, Section B).

<sup>34</sup>See Michael Vitiello, Proposition 215: De Facto Legalization of Pot and the Shortcomings of Direct Democracy, 31 U.

of the medicinal use of marijuana, however, can be traced back thousands of years to ancient, non-Western medicine.

The earliest evidence of the therapeutic use of marijuana was published about five thousand years ago in China under the reign of Chen Nung.<sup>35</sup> Among other things, it was prescribed to treat ‘‘malaria, constipation, rheumatic pains, ‘‘absentmindedness’’, and ‘‘female disorders’’.’’<sup>36</sup> In India as well as Africa, it was used to treat dysentery, malaria, and different fevers.<sup>37</sup> Later, it was also utilized during the Hellenistic eras, and in medieval Europe.<sup>38</sup> It was utilized in England during the seventeenth and eighteenth centuries for everything from treating depression<sup>39</sup> to treating various inflammations.<sup>40</sup>

The use of marijuana derivatives in Western medicine did not reach its heyday, however, until the nineteenth century.<sup>41</sup> In his book, Marijuana, The Forbidden Medicine, Lester Grinspoon writes:

The first Western doctor to extensively study the medical use of cannabis was Dr. W.B. O’Shaughnessy.<sup>44</sup> As a young physician at the College of Calcutta, he became curious about it when he observed its use in India.<sup>45</sup> In order to satisfy himself that it was safe, he tested cannabis on animals.<sup>46</sup>

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Mich. J.L. Ref. 707, 749 (Spring, 1998).

<sup>35</sup>See Grinspoon & Bakalar, supra note 1, at 3.

<sup>36</sup>Id.

<sup>37</sup>See id.

<sup>38</sup>See id.

<sup>39</sup>See id.

<sup>40</sup>“The *New English Dispensatory* of 1764 recommended applying hemp roots to the skin for inflammation, a remedy that was already popular in eastern Europe.” Grinspoon & Bakalar, supra note 1 at 3.

<sup>41</sup>Id. at 4.

<sup>44</sup>See id.

<sup>45</sup>See id.

<sup>46</sup>See Michael Aldrich, History of Therapeutic Cannabis, in Cannabis in Medical Practice 35, 44 (Mary Lynn Mathre,

Once satisfied with its safety, he began testing it on patients, where he discovered cannabis to be a fairly effective analgesic as well as an anticonvulsive remedy for treating the muscle spasms that typically accompanied diseases like tetanus and rabies.<sup>47</sup> He also found that if he gave cannabis tinctures to people stricken with cholera he could “stop the vomiting and diarrhea that make the disease fatal.”<sup>48</sup> In 1842, Dr. O’Shaughnessy returned to England and gave the marijuana derivative cannabis to pharmacists, and U.S. and European doctors started prescribing it for various illnesses and other conditions.<sup>49</sup>

In 1850, it was included in the U.S.’s list of officially recognized medicinal drugs (the Pharmacopoeia). In 1860, the Ohio State Medical Society held the U.S.’s first conference on medicinal marijuana, where they reported “successful treatments of stomach pain, childbirth psychosis, chronic cough, gonorrhea, and marijuana’s general usefulness as an analgesic for inflammatory or neuralgic pains.”<sup>51</sup> Later, the Civil War edition to the U.S. Dispensatory also devoted a number of pages to the usefulness of cannabis as medicine<sup>52</sup>, and noted that cannabis was “a drug that has special value in some morbid conditions and the intrinsic merit and safety of which entitles it to a place once held in therapeutics.”<sup>53</sup> The Dispensatory also noted that cannabis was effective as “a decided aphrodisiac, to increase the appetite, and occasionally to induce the cataleptic state...to cause sleep, to allay spasm, to compose nervous inquietude, and to relieve pain.”<sup>54</sup> It was also specifically recommended cannabis for many convulsive conditions.<sup>55</sup>

By the 1880’s some doctors were even prescribing cannabis as an anti-depressant, using it to

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ed., 1997).

<sup>47</sup>See Mathre, ed., supra note 46, at 44.

<sup>48</sup>Id. at 44-5.

<sup>49</sup>See Grinspoon & Bakalar, supra note 1, at 4.

<sup>50</sup>See Bilz, supra note 5, at 118.

<sup>51</sup>Mathre, ed., supra note 46, at 46.

<sup>52</sup>See id.

<sup>53</sup>Bergstrom, supra note 3, at 158.

<sup>54</sup>Mathre, ed., supra note 46, at 46.

<sup>55</sup>See id.

help alleviate the mental stress in patients who were suffering from terminal illnesses.<sup>56</sup>

The invention of the hypodermic syringe for injecting opiates along with the development of synthetic drugs led to the curtailment of the prevalent use of marijuana as a medicinal agent around the beginning of the twentieth century.<sup>57</sup> The hypodermic needle made opiate painkillers easier to administer, and doctors preferred the superior dosage control that the synthetic drugs purported to offer.<sup>58</sup>

The decreased prevalence of its usage around the beginning of the twentieth century did not, however, signal marijuana's movement from medical agent to illicit substance. Around the same time that medical marijuana prescription decreased, the federal government began passing its first major drug control laws.<sup>59</sup> Interestingly, marijuana was not among the drugs mentioned.<sup>60</sup> Although the prevalence of its prescription by doctors decreased, pharmacists continued to keep it in stock at drug stores along with other remedies right up until the passage of the Marihuana Tax Act in 1937.<sup>61</sup> In fact, even during the legislative hearings for the Marihuana Tax Act itself, C. Hester (Assistant General Counsel for the Treasury Department) indicated that one of the purposes of the tax was to facilitate the use of medicinal marijuana.<sup>62</sup> It was only in 1942, five years after the passage of the Marihuana Tax Act,<sup>63</sup> that marijuana was removed from the U.S. Pharmacopoeia,<sup>64</sup> sparking the debate over medicinal marijuana that continues to this day.

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<sup>56</sup>See Grinspoon & Bakalar, supra note 1, at 5.

<sup>57</sup>See id. at 7.

<sup>58</sup>See id.

<sup>59</sup>See Matthew Segal, Overdue Process: Why Denial of Physician-Prescribed Marijuana to Terminally Ill Patients Violates the United States Constitution, 22 Seattle U. L. Rev. 235, 239 (Summer, 1998).

<sup>60</sup>See id.

<sup>61</sup>See Bergstrom, supra note 3, at 158.

<sup>62</sup>See Bilz, supra note 5, at 120.

<sup>63</sup>See Bergstrom, supra note 3, at 158 (discussed in greater detail infra Chapter 1, Section B).

<sup>64</sup>See Bilz, supra note 5, at 118.



## RECREATIONAL USE

Despite the many applications and potential uses for the marijuana plant in the industrial and medical arenas, the psychoactive use of marijuana for recreational purposes has been the use that has attracted the most attention and generated by far the most controversy in America in the twentieth century. When the Marihuana Tax Act<sup>65</sup> was passed in 1937 severely restricting the trafficking of marijuana regardless of the purpose of the trafficking, the social ill that the Act's proponents claimed the Act would treat was the recreational use of marijuana and the social problems that supposedly accompanied its use in the U.S. during the early 1900's.<sup>66</sup> Interestingly, recreational use of marijuana in the United States had only been at all prevalent for a relatively short period of time before the Marihuana Tax Act was passed and use of any kind effectively became illegal. A look at the history of marijuana use in the U.S. in the years before the passage of the Marihuana Tax Act offers some insight into why recreational marijuana use became such a high-priority social ill so quickly and how the perceived menace of recreational use was used to gain passage of laws that effectively outlawed the industrial and medical use of marijuana as well as its recreational use.

As previously stated above, psychoactive recreational use of marijuana had quite a brief pre-1937 history in the United States. It was a relatively rare phenomenon before the twentieth century, aside from a few cases of experimental use by a few writers of the time.<sup>67</sup> However, recreational use flourished in Central America and Mexico in the late nineteenth century, and soon Mexican agricultural workers in search of jobs in the southwestern U.S. brought with them the practice

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<sup>65</sup>See Bergstrom, supra note 3, at 158 (discussed in greater detail infra Chapter 1, Section B).

<sup>66</sup>See id.

<sup>67</sup>See Himmelstein, supra note 11, at 22. Writers such as Fitzhugh Ludlow and Bayard Taylor had experimented with hashish in the late nineteenth century. See id.

of recreational marijuana use in the early twentieth century.<sup>68</sup> Marijuana use was noted among Mexicans living in Texas in the 1910's and later among Mexicans in the Southwest, West, and even up into Chicago by the 1920's.<sup>69</sup> Marijuana use spread to poor African-Americans in the 1920's, first noted in New Orleans, and later in African-American populations all over the southern and northern U.S.<sup>70</sup> By the time that the Marihuana Tax Act was passed in 1937,<sup>71</sup> African-Americans as well as white musicians involved in the jazz scene were using marijuana recreationally. Contrary to lamentations of much of the anti-marijuana propaganda of the late 1930's, use of marijuana among adolescents did not become a prevalent phenomenon until the 1960's, long after the passage of the Marihuana Tax Act.<sup>72</sup>

There is evidence that the phenomenon of marijuana use by socially marginal groups such as these was a major contributing factor in fostering the anti-marijuana sentiment that led to the passing of the Marihuana Tax Act. During the years before the Act's passage, marijuana was widely associated with African-Americans, Mexicans, and other socially marginal groups that were prejudicially perceived as prone to aggressive and violent behavior.<sup>73</sup> Some historians have argued that marijuana's association with these supposedly violent groups led to its association with the fostering of violent behavior in the minds of the non-marginal population.<sup>74</sup> This association in the minds of the general population of violent behavior with the 'violent' Mexicans may or may not have been a significant public concern in the years leading up to the passage of the Marihuana Tax Act.

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<sup>68</sup>See Id.

<sup>69</sup>See Id.

<sup>70</sup>See Id.

<sup>71</sup>See Bergstrom, supra note 3, at 158 (discussed in greater detail infra Chapter 1, Section B).

<sup>72</sup>See Himmelstein, supra note 11, at 22.

<sup>73</sup>See Bilz, supra note 5, at 119.

<sup>74</sup>See id.

There is still some debate as to whether or not the public's fear of the "violent, doped-up Mexican" was actually widespread, significant, or even genuine.<sup>75</sup> What is not generally open for debate, however, is that the claims (true or not) of public officials that the public was highly concerned about "violent marijuana smokers" certainly contributed significantly to the passage of the Marihuana Tax Act. In his campaign against marijuana in the years prior to the passage of the act, Harry Anslinger (Commissioner of Narcotics at the time) made many claims that marijuana caused violent and aggressive behavior as well as mental deterioration.<sup>76</sup> Moreover, during the hearings in which the Marihuana Tax Act was examined by the House Ways and Means Committee, much of the evidence presented to argue in favor of the Act's passage took the form of newspaper articles noting the prevalence of marijuana addiction and linking it causally to criminal behavior.<sup>77</sup> Thus, though the recreational use of marijuana in the United States had a much shorter pre-Marijuana-Tax-Act chronological history than did its use in medicine or industry, it certainly had the most tumultuous pre-1937 history of the three uses; and it was certainly the first use to become a significant espoused concern of public officials before the passage of the Marihuana Tax Act.

B.

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<sup>75</sup>See Himmelstein, *supra* note 11, at 28-29 (noting that supporters of the anti-Mexican sentiment hypothesis fail to show evidence of significant public concern regarding Mexicans and marijuana use other than letters from a few of Louisiana's local officials and the claims of Harry Anslinger, the Commissioner of Narcotics at the time, that he was responding to a significant public concern.)

<sup>76</sup>See Grinspoon & Bakalar, *supra* note 1, at 7-8.

<sup>77</sup>See *id.*



causally linking marijuana use to the behavior of marginal ethnic groups that were prejudicially perceived as violent at that time.<sup>83</sup> He continually disseminated horror stories about people who committed violent murders, allegedly because they had used marijuana, to the press.<sup>84</sup> His campaign was even responsible for the famous anti-marijuana propaganda film *Reefer Madness*, which was actually regarded as a genuine attempt to address a serious social issue at the time.<sup>85</sup>

Anslinger's anti-marijuana campaign was a far-reaching campaign that influenced virtually all of the information the public received about marijuana during the 1930's and 1940's. Virtually all of the magazine articles in the mid-1930's that called attention to the "marijuana problem" received the information on which they based their contentions from the Federal Bureau of Narcotics.<sup>86</sup> Obviously, such a far-reaching campaign was bound to affect the way that governmental officials addressed the issue of marijuana, and the hysteria generated by Anslinger's campaign led to the incorrect classification of marijuana as a narcotic.<sup>87</sup> This mis-classification led policymakers to model the first twentieth-century marijuana legislation after other pieces of narcotics legislation rather than after post-prohibition-alcohol or tobacco legislation.<sup>88</sup> Anslinger's campaign eventually led to the promulgation of the Marihuana Tax Act, America's first anti-marijuana legislation, in 1937.<sup>89</sup> Under this legislation;

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<sup>83</sup>See Vitiello, *supra* note 34, at 776.

<sup>84</sup>See Bilz, *supra* note 5, at 120.

<sup>85</sup>See Grinspoon & Bakalar, *supra* note 1, at 7-8.

<sup>86</sup>See Himmelstein, *supra* note 11, at 25.

<sup>87</sup>See Bilz, *supra* note 5, at 119.

<sup>88</sup>See *Id.*

<sup>89</sup>See Bilz, *supra* note 5, at 120.

The legislation made marijuana for any purpose other than medical use prohibitively expensive. Moreover, it made even medical use virtually impossible because of extensive paperwork requirements placed on doctors attempting to use it.<sup>91</sup> The Act also contained a tax stamp requirement for all sales of hemp products, which the federal government almost invariably refused to issue.<sup>92</sup> The combination of financial and bureaucratic obstacles effectively eliminated legal dealings in hemp products, regardless of purpose.<sup>93</sup>

The influence of Anslinger's anti-marijuana campaign over policymakers' propagation of the Marihuana Tax Act is evident in both the information that they used to justify the need for the Act and the reactions of policymakers when medical experts criticized the evidentiary basis for their claims that the Act was necessary. During the 1937 hearings in which the House Ways and Means Committee examined the Marihuana Tax Act, W.C. Woodward, a representative of the American Medical Association who supported Congress's aims but lobbied for less restrictive legislation to protect marijuana's medical potential pointed out that Congress had virtually no empirical medical proof that marijuana was addictive, prominently used by adolescents, or causally connected to violent behavior.<sup>94</sup> He pointed out that all the evidence on which they based the need for this legislation came in the form of newspaper articles, and not from medical sources.<sup>95</sup>

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<sup>91</sup>See id.

<sup>92</sup>See Bergoffen & Clark, supra note 7, at 122.

<sup>93</sup>See id.

<sup>94</sup>See Grinspoon & Bakalar, supra note 1, at 8-9.

<sup>95</sup>See id.

Due to the politically charged nature of this issue that resulted from Anslinger's campaign, however, Woodward's criticisms of the quality of legislators' evidence base only served to turn legislators against him. They questioned him critically about everything from his educational background to his relationship to the American medical Association, never seriously considering the merits of his objections to their evidence base, until they finally cut him out of the discussion once and for all, admonishing him for throwing "obstacles in the way of something that the Federal Government is trying to do."<sup>96</sup> Thus, despite the lack of any evidence of the significant societal harms of marijuana other than various news articles, most of which were fed to the press by the Federal Bureau of Narcotics, the Marihuana Tax Act was signed on August 2, 1937,<sup>97</sup> effectively eliminating the legal use of marijuana for any purpose. Up until the passage of the Marijuana Tax Act, Anslinger's anti-marihuana campaign appeared to be aimed at eliminating only the recreational use of marijuana. In fact, during the legislative hearings for the Marihuana Tax Act, C. Hester (Asst. General Counsel for the Treasury Department and a witness in the hearings) actually testified that one of the purposes for which the marijuana tax money would be used was to facilitate the medical use of marijuana.<sup>98</sup> However, Anslinger's anti-marijuana campaign eventually began to focus on eliminating the use of marijuana in the medical realm as well. The Bureau began making it increasingly difficult to obtain marijuana for scientific studies, and when studies were possible, the Bureau would only accept as legitimate those studies that painted a negative picture of marijuana.<sup>99</sup> Marijuana was removed from the Pharmacopoeia in 1942.<sup>100</sup> Finally, Anslinger turned his attention to aligning the dominant medical opinions with the Bureau's anti-marijuana platform.

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<sup>96</sup>Id. at 10-11.

<sup>97</sup>See Bilz, supra note 5, at 120.

<sup>98</sup>See id.

<sup>99</sup>See id. at 120-121.

<sup>100</sup>See id. at 118.

Shortly after the passage of the Marihuana Tax Act, New York's Mayor La Guardia formed a large team of M.D.'s and Ph.D.'s to study the sociological, medical, and psychological consequences of marijuana use in New York City.<sup>101</sup> The report, published in 1944, concluded that there was no proof that marijuana caused violent, aggressive behavior.<sup>102</sup> Even before the report was published in 1944, Anslinger undermined and suppressed it. In 1942 when the Journal of the American Medical Association published an editorial that validated the La Guardia study as 'a careful study', and actually mentioned a few of marijuana's potential medical uses, Anslinger quickly responded, writing a letter to the AMA Journal severely criticizing the La Guardia study.<sup>103</sup>

Mysteriously, at that point, the American Medical Association 'made an extraordinary about-face and joined the Federal Bureau of Narcotics in the denunciation of the La Guardia Report.'<sup>104</sup> The Journal then published an editorial that advised policymakers to disregard such an 'unscientific' study and to 'continue to regard marihuana as a menace wherever it is purveyed.'<sup>105</sup> Although it has stopped publishing evidentiarily weak papers lamenting the dangers of marijuana use,<sup>106</sup> the Journal remained consistently weary of indicating opinions that would inject it in any significant way into the politics associated with the marijuana issue from that point, and for years afterward.<sup>107</sup> Anslinger had, with the final suppression of all opposing medical evidence, ushered in an era of anti-marijuana sentiment that would dominate America's overall opinion regarding marijuana, regardless of the purpose of its use, from 1944 until the 1960's when

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<sup>101</sup>See id. at 121.

<sup>102</sup>See id.

<sup>103</sup>See id. at 120.

<sup>104</sup>Bilz, id. at 121-122.

<sup>105</sup>Bilz, id. at 122.

<sup>106</sup>See id.

<sup>107</sup>See id.



recreational use increased again.<sup>108</sup>

It is clear that, whatever the factors were that contributed to the desire of governmental policymakers to pass anti-marijuana legislation, the factors were grounded less in empirical medical evidence of marijuana's effect on human behavior than they were in other more political factors. 35 years after the passage of the Marihuana Tax Act, the National Commission on Marijuana and Drug Abuse reexamined the Act and found that the Act was misguided and generally based on misguided and incorrect hypotheses.<sup>109</sup>

It is also clear that Harry Anslinger's personal fanatical hatred of drugs single-handedly played a large role in powering the late-1930's anti-marijuana movement. There are several indications that paper and textile manufacturers, chemical companies and other industries that competed with the hemp industry in the in the production of paper and other hemp products also applied some of the pressure to policymakers that resulted in the passage of the Marihuana Tax Act.<sup>110</sup> These industries, after all, were some of the biggest proponents of the Marihuana Tax Act besides the drug enforcement officials.<sup>111</sup> However, while pressure from Anslinger or from competing industries on federal policymakers may explain the passage of the Marihuana Tax Act, it fails to explain the public concerns that sparked the passage of the many state and local anti-marijuana laws that followed the Marihuana Tax Act<sup>112</sup> and indicated the increased entrenchment of anti-marijuana public sentiment that is still prominent today.

In order for Harry Anslinger and other proponents of sweeping anti-marijuana legislation still

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<sup>108</sup>See Grinspoon & Bakalar, supra note 1, at 13.

<sup>109</sup>See Vitiello, supra note 34, at 751.

<sup>110</sup>See Bergstrom, supra note 3, at 158.

<sup>111</sup>See id. In fact, there are even indications that Harry Anslinger had significant ties to some of the hemp industry's biggest industrial competitors. Andrew Mellon, President Hoover's Secretary of the Treasury in 1931, is the one who appointed Harry Anslinger (his future nephew-in-law) to the office of Commissioner of Narcotics. Interestingly, Andrew Mellon was also the Mellon of the Mellon Bank of Pittsburgh, and the chief financial backer of the DuPont company, which was one of the chief competitors with the hemp industry in the arenas of both paper-manufacture and the manufacture of plastics. See Herer, supra note 4, at 24.

<sup>112</sup>See Grinspoon & Bakalar, supra note 1, at 11.

needed a way to garner public support for their anti-marijuana cause so that the movement could weather the accusations that proponents of the Marihuana Tax Act had no evidence to prove that marijuana actually caused the problems they said it did. The key that the Act's proponents found to mobilizing public sentiment against marijuana was in mobilizing the non-marginal public's racist sensibilities. Racist sentiments toward Mexicans and African-Americans that predominated the U.S. early in the twentieth century played a key role in enabling crusaders like Harry Anslinger to push the Marihuana Tax Act through to passage despite a lack of empirical evidence of marijuana's harmful effects.

Negative symbolic images associating marijuana almost entirely with recreational use by marginal social and ethnic groups played a key role in generating the negative public attitudes toward marijuana that enabled federal anti-drug agencies to get marijuana banned completely despite its many medical and industrial applications. There is still some disagreement over between those who argue that a genuine public concern over the image of the "Mexican dope-smoking menace" necessitated the passage of anti-marijuana legislation and those who argue that Harry Anslinger created the image of the "Mexican dope-smoking menace" to garner enough support to gain the passage of anti-marijuana legislation. There is little argument, however, that these racist and classist associations, regardless of their source, politically charged the marijuana debate and focused attention on images of recreational use to such a large extent that rational discussion of marijuana in any other context became virtually impossible. The argument that the symbolic association of marijuana with marginal racial and social groups created much of the anti-marijuana sentiment that led to the passing of the Marihuana Tax Act is grounded in an examination of the demographics of the population of marijuana-smokers in

the early 1900's.<sup>113</sup> The prevalent use of marijuana in the United States began with Mexican migrant workers, then moved on to other prejudicially perceived groups such as African-Americans, and members of the jazz scene in the 20's and 30's.<sup>114</sup> During the depression, marginal groups such as Mexicans came to be viewed as a distinct and unwelcome surplus, which heightened prejudicial attitudes toward them as the depression wore on. Because the non-marginal white populace viewed Mexicans as prone to violent and aggressive behavior<sup>115</sup> and widely associated marijuana-smoking with Mexicans, marijuana came to be widely causally associated with the socially undesirable behavior in which these groups engaged.<sup>116</sup> Thus, so the argument goes, local government officials responded to this public outcry by lobbying people like Harry Anslinger to pass some kind of law to stave off the onslaught of the "marijuana menace" that was sweeping the country.<sup>117</sup>

The argument that anti-marijuana legislation was a response to racist and classist associations with marginal minority groups (Mexicans, in particular) does have some evidentiary support. The hysteria surrounding marijuana use due in large part to its association with minority groups caused it to be mis-classified as a narcotic<sup>118</sup>, and legislation concerning marijuana was consequently modeled after other narcotics legislation rather than post-prohibition alcohol, or tobacco legislation.<sup>119</sup> In addition, Harry Anslinger himself claimed that his push for the Marihuana Tax Act was simply a response to local requests for a solution the "marijuana problem".<sup>120</sup> Critics of the theory that Anslinger's anti-marijuana campaign was simply a response to the

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<sup>113</sup>See Himmelstein, supra note 11, at 27-30.

<sup>114</sup>See Bilz, supra note 5, at 119.

<sup>115</sup>See id.

<sup>116</sup>See Himmelstein, supra note 11, at 28.

<sup>117</sup>See id.

<sup>118</sup>See Bilz, supra note 5, at 119.

<sup>119</sup>See Id.

<sup>120</sup>Himmelstein, supra note 11, at 28.

public's demands argue that Anslinger often exaggerated the public concern with the marijuana issue<sup>121</sup>, and point to the fact that Anslinger offered only a few letters as proof of public concern and most of them did not even specifically mention Mexicans. Even if Anslinger exaggerated the public's concern with the phenomenon of Mexican marijuana-smokers or the public's belief that marijuana use presented a significant social problem, racist and classist images associated with marijuana still almost certainly powered the movement toward anti-marijuana legislation. Anslinger himself believed that Mexicans were responsible for the marijuana problem,<sup>122</sup> and he unabashedly played on and evoked the anti-Mexican and anti-African-American sentiment that did exist in order to further his public anti-marijuana propaganda campaign.<sup>123</sup> He disseminated stories through the Bureau of Narcotics about "colored" college students smoking marijuana with white female students and getting them pregnant, or about "Negroes" high on marijuana kidnapping young girls and infecting them with STD's, in order to garner public support for anti-marijuana legislation.<sup>124</sup>

Thus, even if the anti-Mexican sentiment in society during the first part of the twentieth century did not directly precipitate anti-marijuana legislation, Anslinger certainly capitalized on what anti-Mexican sentiment did exist to bring anti-marijuana legislation to pass. He worked hard to solidify an image of marijuana that inextricably linked it with visions of doped-up Mexicans wreaking havoc on society, and this symbolism whipped up an atmosphere surrounding marijuana so emotional and politically charged that medical experts who dared ask for empirical proof that marijuana actually led to the violence and aggression that Anslinger claimed it did, policymakers chastised these experts for "getting in the way of something the government

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<sup>121</sup>See id. at 29.

<sup>122</sup>See Vitiello, supra note 34, at 776.

<sup>123</sup>See id.

<sup>124</sup>See id.

was trying to do.’’<sup>125</sup> Once such emotion was stirred up, the empirical evidence was of little consequence and passage of the Marihuana Tax Act and of the state-level anti-marijuana legislation that followed became inevitable.

As a result of the war against marijuana and the image of the ‘‘killer weed’’ that Harry Anslinger hammered into the public conscience, the legal treatment of marijuana during the decades between the passage of the Marihuana Tax Act and the 1960’s consisted of the outlawing of marijuana possession and sale at both state and federal levels and the systematic escalation of criminal sanctions for either offense.<sup>126</sup> The decade of the 1960’s, however, brought with it a crumbling of the public consensus regarding marijuana, its dangers, and the legitimacy of the sanctions imposed on marijuana users.<sup>127</sup> The 1960’s marked the beginnings of a struggle that continues to this day between those who contest the time-honored prohibitions of the past two decades and the governmental establishment, which continues to cling to the classifications of the Anslinger regime despite mounting evidence that those classifications are based on faulty and highly political premises.

Marijuana use became prominent again in the 1960’s, this time among middle-class youth<sup>128</sup>, and the Marihuana Tax Act was found unconstitutional in 1969.<sup>129</sup> In response to the unenforceability of the Marihuana Tax Act as well as legislative concern about the resurgence of recreational drug use, Congress passed the Controlled Substances Act of 1970.<sup>130</sup> This Act placed all controlled substances into one of five ‘‘Schedule’’ categories, Schedule I being the most restrictive

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<sup>125</sup>See Grinspoon & Bakalar, *supra* note 1, at 9-11.

<sup>126</sup>See Himmelstein, *supra* note 11, at 3-4.

<sup>127</sup>See *id.* at 4.

<sup>128</sup>See *id.* at 30.

<sup>129</sup>See Bergstrom, *supra* note 3, at 160.

<sup>130</sup>See Mathre, ed., *supra* note 46, at 49-50.

and Schedule V being the least restrictive, depending on the substance's potential for abuse.<sup>131</sup> Interestingly, the initial decisions about which drugs were placed on which schedules were made, much like the decision to pass the Marihuana Tax Act decades earlier, without any authoritative input from medical experts. Instead, the Justice Department---Attorney General John Mitchell in conjunction with the Drug Enforcement Agency (formerly the Federal Bureau of Narcotics)---made the final decision as to what substances were categorized under which schedules.<sup>132</sup> Not surprisingly, these officials placed marijuana on Schedule I, the most restrictive schedule.<sup>133</sup> In placing marijuana on Schedule I the DEA labeled marijuana a drug with no medical utility as well as a high potential for abuse that could not be safely prescribed even under the care of a physician.<sup>134</sup> The chief consequence of this classification was that marijuana could not be prescribed even by physicians and could only be researched after the filing of special applications with various federal agencies.<sup>135</sup> Ironically, even as public sentiment began to change regarding marijuana and its use, Congress passed legislation that usurped the medical community's control over whether or not it could utilize marijuana and reflected the same image-based anti-marijuana sentiment that had permeated the Anslinger era decades earlier. The contention over the marijuana issue became even more starkly evident roughly a year later when President Nixon, looking once and for all to establish conclusive evidence of marijuana's dangers to justify its severe restriction, established the National Commission on Marijuana and Drug Abuse to look into the marijuana problem.<sup>136</sup> To Nixon's dismay, the commission found that the original laws that outlawed were based on misguided and incorrect speculation regarding

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<sup>131</sup>See Mary Lynn Mathre, Introduction, to **Cannabis in Medical Practice** 4 (Mary Lynn Mathre, ed., 1997).

<sup>132</sup>See id. at 49-50.

<sup>133</sup>See id.

<sup>134</sup>See id.

<sup>135</sup>See Mathre, ed., supra note 131, at 4.

<sup>136</sup>See Vitiello, supra note 34, at 752.

marijuana's effects and social impact<sup>137</sup>, and recommended that the law be changed to decriminalize the possession of marijuana when for personal use.<sup>138</sup> In what has become the all-too-typical response of policymakers when confronted with an argument that questions the accuracy of the Anslinger vision of marijuana's dangers, Nixon responded by divorcing himself from his own commission before the recommendations were even published and proclaiming that he would simply refuse to follow any recommendation that involved the legalization of marijuana.<sup>139</sup> Turning a blind eye yet again to any evidence that contradicted Anslinger's anti-marijuana platform or the accuracy of the 'killer weed' image, policymakers dismissed the Commission's recommendations, and the politically-based prohibitions continued.

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<sup>137</sup>See id. at 751-2.

<sup>138</sup>See id. at 752.

<sup>139</sup>See id.





IND'' program reflected the government's continued ''Anslingerian'' inability to dissociate itself from its fears of recreational marijuana use long enough to examine marijuana's therapeutic potential objectively.

The government's battle against pro-medical-marijuana groups to keep marijuana classified as a Schedule I substance began when NORML filed its first rescheduling petition with the Bureau of Narcotics and Dangerous Drugs (BNDD, and the future DEA). Congress granted the right of schedule challenges to interested parties who wished to do so and secured for those parties the right to a hearing on their challenges as part of the Controlled Substances Act in 1970.<sup>142</sup> It did so in order to allow for the reclassification of substances in the event that continued research of a their properties led to the discovery of new medical benefits or other properties that rendered it's classification incorrect or obsolete.<sup>143</sup> Just two years after the passage of the Controlled Substances Act, NORML put this rescheduling clause to the test by filing the first rescheduling petition in 1972.<sup>144</sup> The BNDD reacted to this petition swiftly and negatively. Without even holding the hearings called for in the Controlled Substances Act, the Bureau refused to even file the petition, claiming that the requirements of a treaty signed at a 1961 international anti-drug convention did not permit them to file such a petition.<sup>145</sup> NORML appealed this summary dismissal to the D.C. Circuit, and the court found in NORML's favor.<sup>146</sup> The court ruled that such a dismissal without any merit-based findings contradicted the administrative process,

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<sup>142</sup>See Bilz, supra note 5, at 124.

<sup>143</sup>See id.

<sup>144</sup>See Segal, supra note 59, at 243.

<sup>145</sup>See id.

<sup>146</sup>See id.

which called for findings on the merits.<sup>147</sup>

On remand in 1975, the Administrative Law Judge assigned to the case found that the 1961 treaty did not prevent the rescheduling of marijuana as asserted by the BNDD, and proposed that the proper response to the petition for the BNDD would be to hold the rescheduling hearings on the issue that the Controlled Substances Act called for.<sup>148</sup> As if neither the Court of Appeals nor the Administrative Law Judge had said a word about the necessity of holding the hearings on the rescheduling matter, however, the Acting Administrator of the BNDD (now renamed the DEA) issued a final order that denied the petition without any hearings on the matter.<sup>149</sup>

The petitioners again appealed the summary petition dismissal to the D.C. Circuit, and again the Court of Appeals ordered the DEA to comply with the rule-making procedures of the Controlled Substances Act, and hold hearings.<sup>150</sup> This time, the court also ordered the DEA to submit the petition to the Department of Health, Education, and Welfare.<sup>151</sup> The DEA did comply with the order to refer the petition to the Department of Health, Education, and Welfare. However, when they issued a recommendation in 1979 that marijuana remain on Schedule I, the DEA summarily denied the rescheduling petition without holding the required hearings yet again.<sup>152</sup>

For a third time, the petitioners appealed the DEA's summary denial to the D.C. Circuit. Again, the court remanded the case and instructed the DEA to submit the case to the Department of Health and Human Services (formerly the Department of Health, Education and Welfare) for scientific

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<sup>147</sup>See id.

<sup>148</sup>See id.

<sup>149</sup>See id.

<sup>150</sup>See id. at 244.

<sup>151</sup>See id.

<sup>152</sup>See id.

evaluation, and to hold the required hearings on the matter.<sup>153</sup> Finally, in 1986, the DEA complied and announced that hearings on the rescheduling of marijuana would be held before Administrative Law Judge Francis Young.<sup>154</sup> The hearings commenced in the summer of 1986, and continued for two years.<sup>155</sup> Finally, in 1988, Judge Young issued a ruling rejecting the standards the DEA used to determine that marijuana did not have an accepted medical use.<sup>156</sup> He determined that marijuana should be deemed to have an accepted medical use (and should, therefore, be moved to Schedule II) as long as a respectable minority in the medical community supported its use in medical treatments.<sup>157</sup> True to its unrelenting anti-marijuana stance, the DEA disregarded the recommendations of its own judge, and denied the petition using the same eight-factor “‘accepted medical use’” test that Judge Young rejected to determine that marijuana did not have an accepted medical use.<sup>158</sup> Interestingly, several of these factors were impossible to satisfy for any drug with a Schedule I classification. The requirement that a drug have general use and acceptance before being removed from Schedule I, for example, would be impossible to meet because the government’s restrictions on Schedule I substances would prevent any general use or acceptance.<sup>159</sup> Thus, the petitioners appealed a fourth time in 1991.<sup>160</sup> This time, the petition was ordered returned to the DEA for reconsideration of the factors used to determine medical acceptability.<sup>161</sup> The DEA responded in 1992 by reworking the medical acceptability test, removing the “‘impossible

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<sup>153</sup>See id.

<sup>154</sup>See id.

<sup>155</sup>See Grinspoon & Bakalar, supra note 1, at 14.

<sup>156</sup>See Vitiello, supra note 34, at 753-754.

<sup>157</sup>See id.

<sup>158</sup>See Grinspoon & Bakalar, supra note 1, at 16. The criteria that the DEA used to determine whether or not a substance had an accepted medical use were as follows: “(1) scientifically determined and accepted knowledge of its chemistry; (2) scientific knowledge of its toxicology and pharmacology in animals; (3) effectiveness in human beings established through scientifically designed clinical trials; (4) general availability of the substance and information about its use; (5) recognition of its clinical use in generally accepted pharmacopoeia, medical references, journals, or textbooks; (6) specific indications for the treatment of recognized disorders; (7) recognition of its use by organizations or associations of physicians; and (8) recognition and use by a substantial segment of medical practitioners in the United States.” Id.

<sup>159</sup>See Segal, supra note 59, at 245.

<sup>160</sup>See Grinspoon & Bakalar, supra note 1, at 17.

<sup>161</sup>See Vitiello, supra note 34, at 754-755.

factors'', disavowing any use of the ''impossible factors'' in their previous rejection of the rescheduling petition, and denying the petition again.<sup>162</sup> The petitioners appealed a fifth time, this time alleging DEA bias in the decision-making process and objecting to allegedly variant evidentiary standards utilized by the DEA in their decision-making processes.<sup>163</sup> This time, however, the court denied their appeal, finding no prejudicial influence in the evidentiary standard, and the DEA issued a final denial of the marijuana rescheduling petition in 1994.<sup>164</sup>

Thus, 22 years, five appeals, and two adverse Administrative Law Judge opinions later, the BNDD/DEA had achieved final and total official legal validation of their contention that marijuana does not have medical utility under federal law despite significant evidence from the 1988 hearings that it does. This 22-year-long refusal to even explore the possibility that marijuana might have some large-scale medical utility regardless of the sentiment in the medical community seems like the typical anti-marijuana stance that drug enforcement agencies have been taking since the Anslinger era beginning in the 1930's. However, the court's ultimate validation of the Schedule I status of marijuana might cause one to question whether marijuana's prohibition still generally stems from emotion-based negative symbolism, as it did during the Anslinger era, or stems from new and more objective medical considerations.

The question of whether the primary motivations for the continued governmental resistance to legalization of medicinal marijuana since 1970 are based in political considerations or medical considerations is answered in large part by the government's quiet recognition of marijuana's

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<sup>162</sup>See Segal, *supra* note 59, at 245-246.

<sup>163</sup>See *id.* at 246.

<sup>164</sup>See *id.*

medical potential through the ‘‘Compassionate IND’’ program during its legal battle with NORML. Even as the FBN/DEA was using every procedural means necessary to avoid even considering marijuana’s medical utility in 1976, Congress created the ‘‘Compassionate IND’’ program, which allowed people in need of medical marijuana to obtain government-grown marijuana for therapeutic use.<sup>165</sup> The history of this program, and of the circumstances behind its eventual termination in 1992<sup>166</sup> illustrate yet again the extent to which the federal drug enforcement agencies’ collective inability to separate medical marijuana use from recreational marijuana use continues to drive the government’s public denial of marijuana’s medical potential even as it quietly recognizes that potential out of the public eye. From 1976 to 1988, the government quietly provided a small number of medical patients with government-grown marijuana for therapeutic use even as it vigorously denied marijuana’s medical utility in its rescheduling legal battles.<sup>167</sup> The government left this program alone until events from 1989 to 1991 threatened to expand both the number of patients in the program and the publicity surrounding the program. At that time, the Bush administration ordered the FDA to shut down the program, not because marijuana’s medical utility had suddenly come into question, but because the Bush administration felt that the program may send a ‘‘bad message’’ about marijuana use that could undermine its overall anti-drug stance.<sup>168</sup> A more detailed look into the program’s history further illustrates this point.

In 1976, the government officially kicked off the Compassionate IND Program when Robert Randall, a glaucoma patient,<sup>169</sup> became the first recipient of government-grown medical marijuana under

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<sup>165</sup>See Crites-Leoni, *supra* note 140, at 277-278.

<sup>166</sup>See Grinspoon & Bakalar, *supra* note 1, at 22.

<sup>167</sup>See Crites-Leoni, *supra* note 140, at 277-278.

<sup>168</sup>See Vitiello, *supra* note 34, at 757.

<sup>169</sup>Robert C. Randall & Alice M. O’Leary, *Marijuana Rx: The Patient’s Fight for Medicinal Pot* 4 (1998).

the program.<sup>170</sup> The marijuana was, and still is, grown on a government farm at the University of Mississippi at Oxford under the supervision of the National Institute of Drug Abuse.<sup>171</sup> For 12 to 13 years after Randall first began receiving medical marijuana under this program, the government recognized the medical utility of marijuana in at least six other instances, providing marijuana under the Compassionate IND Program to roughly a half of a dozen other medical patients. Through 1988, the government allowed this program to run relatively unhindered. It seemed that as long as the program remained small and out of the public eye, the government was willing to quietly allow access to the medical benefits of marijuana to a few people who needed it. However, several events that occurred beginning in 1989 would ensure that the Compassionate IND Program would not remain a small, low-profile program for long.

During the late 1980's, the process for applying for a Compassionate IND was streamlined from an application that took as many as 50 hours to finish down to an application that could be completed in as little as an hour.<sup>172</sup> This removed many of the bureaucratic obstacles that had often discouraged people from seeking marijuana through the program. This streamlined process, along with publicity from a Harvard survey regarding the medical benefits of marijuana led to a surge in Compassionate IND applications,<sup>173</sup> and by the end of 1989 the number of patients receiving the marijuana under the program had risen sharply to 34.<sup>174</sup> The government's Compassionate IND Program received yet more unwanted publicity as a result of the highly publicized case of Kenneth and Barbra Jenks, who had contracted AIDS and had been arrested for using marijuana

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<sup>170</sup>See Grinspoon & Bakalar, *supra* note 1, at 21.

<sup>171</sup>See Vitiello, *supra* note 34, at 755-756.

<sup>172</sup>See *id.* at 756-757.

<sup>173</sup>See Bilz, *supra* note 5, at 132-133.

<sup>174</sup>See Crites-Leoni, *supra* note 140, at 277-278.

to relieve nausea and vomiting caused by the AIDS treatment drug AZT.<sup>175</sup> The Jenkses were able to successfully defend the criminal charge against them by claiming medical necessity,<sup>176</sup> and they obtained a Compassionate IND in 1991.<sup>177</sup> The case received much publicity, and as a result, the FDA found itself swamped with Compassionate IND applications from AIDS patients seeking similar AZT relief.<sup>178</sup>

Before the surge in the size and publicity of the Compassionate IND Program from 1989 to 1991 the program's size allowed it to exist largely outside of the political debate over recreational drug use, where the issue of marijuana's medical utility was less clouded by federal drug enforcement agencies' traditional platform of antipathy toward marijuana. However, the program's newly heightened profile placed it squarely at odds with an institutionalized anti-marijuana governmental platform that had continually defied medical authority since the early 1930's.

Not surprisingly, the Compassionate IND Program did not last long once it clashed with the DEA's anti-marijuana juggernaut. Interestingly, even as the FDA was making plans to suspend the program, others in the government continued to recognize the medical utility of marijuana and assure interested parties that they would continue to be able to have access to its benefits. Deputy National Drug Control Policy Director Herbert Kleper, for example, stated on national television that anyone who legitimately needed the medical benefits that marijuana provided would continue to be provided with access through the Compassionate IND Program.<sup>179</sup> However, shortly after this very statement the FDA, under pressure from the Bush administration, suspended

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<sup>175</sup>See Grinspoon & Bakalar, supra note 1, at 21.

<sup>176</sup>See id. at 21-22.

<sup>177</sup>See id. at 22.

<sup>178</sup>See id.

<sup>179</sup>See id.

the Compassionate IND Program and stopped processing new applications.<sup>180</sup>

The reasons for this announced suspension indicated again that the government's fear of the idea of recreational use was still as strong as it had been in 1937, and continued to preclude any rational discussion of marijuana's potential medical utility. James O. Mason, chief of the Public Health Service, indicated in no uncertain terms that the chief reason for the suspension of the program was because the Bush administration feared that legalized medical use of marijuana would undercut the administration's staunch opposition to the use of illegal drugs.<sup>181</sup> Mason indicated that "if it is perceived that the Public Health Service is going around giving marihuana [sic] to folks, there would be a perception that this stuff can't be so bad...It gives a bad signal."<sup>182</sup> Mason did make a token attempt to provide a medical basis for discontinuing the program and denying marijuana to the many AIDS-patient-applicants, calling into question the notion that marijuana held any medical utility for AIDS sufferers.<sup>183</sup> He claimed that there was not "a shred of proof" that marijuana offered any assistance to people with AIDS.<sup>184</sup> His contention that marijuana holds no medical utility was also dubious to say the least, in light of the fact that in that same year the FDA clearly recognized its marijuana's utility for AIDS patients when it approved a synthetic form of THC (the purported active ingredient in marijuana) called Marinol for use for treating rapid weight-loss in AIDS patients.<sup>185</sup>

Apparently, the Bush administration feared that the medical use of marijuana by patients with a legitimate need was so intertwined with recreational use by drug users that it could not

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<sup>180</sup>See id.

<sup>181</sup>See id.

<sup>182</sup>Id.

<sup>183</sup>See id.

<sup>184</sup>Id.

<sup>185</sup>See Bergstrom, supra note 3, at 163.



sanction one without implicitly sanctioning the other. This rationale is rather dubious, however, when one considers that current federal law still recognizes the medical utility of other equally dangerous and far more addictive targets of DEA enforcement such as cocaine and morphine despite the substantial social dangers that are associated with recreational use of those drugs.<sup>186</sup> The traditionally close association of marijuana with the recreational drug culture in the eyes of drug enforcement officials since 1937 has apparently made it impossible even today for the federal drug enforcement agencies to separate the potential benefits of marijuana's medical use from the potential dangers of its recreational use in the same way it has done so with drugs like cocaine and morphine. Consequently, as the federal drug enforcement agencies' recent schizophrenic policies of publicly denying marijuana's medical utility even while the FDA quietly recognizes its medical utility on a smaller scale indicated, governmental policies concerning medical marijuana continue to be characterized by an almost pathological refusal to accept marijuana's medical utility for fear that such recognition might encourage recreational use. The same fear of the idea of recreational marijuana use that motivated Harry Anslinger to tax all marijuana use regardless of medical utility in the 1930's has also motivated the federal drug enforcement agencies' refusal to reschedule marijuana regardless of medical utility from the 1970's to the present.

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<sup>186</sup>See Mathre, ed., supra note 131, at 4, citing the presence of cocaine and morphine on the less restrictive Schedule II, for dangerous drugs that nevertheless have a recognized medical utility, under the Controlled Substances Act of 1970. Marijuana remains on Schedule I, a more restrictive classification for substances with no recognized medical utility. See id.

# Chapter Two

## INTRODUCTION

The DEA's refusal to reschedule marijuana has created a nearly insurmountable obstacle for proponents of medicinal marijuana seeking to gain acceptance for its medical use. The Food, Drug and Cosmetic Act of 1938 (as revised in 1962) provides a procedure through which those who seek the approval of the Food and Drug Administration to commercially manufacture and market any chemical substance "affecting bodily structure or function in the absence of disease" can normally do so.<sup>187</sup> This act provides that a sponsor seeking to use or market a substance for therapeutic purposes can obtain FDA-approval to do so by conducting well-controlled clinical studies of the substance that prove to the FDA's satisfaction that it is both safe for human consumption and effective in treating a particular medical condition.<sup>188</sup>

However, marijuana's current status as a Schedule-I substance under the Controlled Substances Act makes it next to impossible for anyone seeking to study the medicinal attributes of a Schedule-I substance to obtain permission to do so.<sup>189</sup> Marijuana's Schedule-I status has essentially eliminated any substantive authority that the FDA would otherwise have over determining the medical potential of marijuana and placed the final determination of marijuana's medical utility in the hands

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<sup>187</sup>Scott Batterman, Brother Can You Spare a Drug: Should the Experimental Drug Distribution Standards Be Modified in Response to the Need 19 *Hofstra L. Rev.* 191, 197 (Fall, 1990); See also id. at 201.

<sup>188</sup>See Peter Barton Hutt & Richard A. Merrill, Food and Drug Law 513 (Peter Barton Hutt & Richard A. Merrill, eds., 2d ed., 1995).

<sup>189</sup>See Nicole Dogwill, The Burning Question: How Will the United States Deal With the Medical-Marijuana Debate?, 1998 *Det. C.L. Mich. St. U. L. Rev.* 247, 249 (Spring, 1998).

of the DEA Administrator.<sup>190</sup> With the FDA relegated to an consultative role in determining marijuana's medical utility as long as marijuana remains a Schedule-I drug,<sup>191</sup> the DEA possesses almost total discretion not only in the determination of marijuana's medical utility but also in the decision as to whether or not to even allow marijuana's medical potential to be studied.<sup>192</sup> The DEA has used this discretion to prevent the study of marijuana's medical potential with a circular line of reasoning that justifies marijuana's Schedule-I status by pointing to the lack of scientific studies demonstrating its safety and medical efficacy but impedes all efforts to study marijuana's safety or medical efficacy citing marijuana's Schedule-I status.<sup>193</sup> This chapter describes the difficult, expensive, and time-consuming process that would have to be followed under current federal law to have marijuana rescheduled to allow for medical study and eventually gain FDA approval to market it for therapeutic purposes. Section A discusses the FDA's role, first in the rescheduling process, and then in the process for approving a substance for general marketing and use as a therapeutic substance. Section B illustrates the argument that although marijuana's approval for therapeutic uses would be by no means guaranteed even if the FDA had the authority to permit an examination of marijuana's medical potential, the DEA's consistent and unwavering refusal to reschedule marijuana to allow for the study of marijuana's medical potential ensures that proponents of marijuana will never have the opportunity to examine marijuana's medical potential using the FDA's standards.

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<sup>190</sup>See *id.*

<sup>191</sup>Hearings Before the Subcomm. on Oversight and Investigations Comm. on Commerce in the U.S. House of Representatives (March 11, 1999) (statement of Nicholas Reuter, MPH Associate Director for Domestic and International Drug Control, Office of Health Affairs, Food and Drug Administration, Department of Health and Human Services). <<http://www.fda.gov/ola/substance.html>>.

<sup>192</sup>See Dogwill, *supra* note 189, at 249.

<sup>193</sup>See Vitiello, *supra* note 34, at 755.

#### A. THE LONG PROCESS NECESSARY TO GAIN THERAPEUTIC

##### ACCEPTABILITY FOR MARIJUANA UNDER FEDERAL LAW

Because marijuana is classified as a Schedule-I substance, anyone seeking the right to study the medicinal attributes of marijuana must complete a rigorous application process in which they must attempt to convince the DEA that marijuana is safe enough and has enough medical potential to allow the study of its medical attributes.<sup>194</sup> The DEA Administrator has the final say-so on the approval or rejection of this application,<sup>195</sup> and the FDA's role in the process is limited to that of an informational consultant to the DEA.<sup>196</sup> Only after the DEA administrator approves the application to study marijuana and the clinical tests begin does the FDA's role in determining the therapeutic utility of marijuana become anything more authoritative than that of an advisor.

Anyone who wishes to study the medicinal qualities of marijuana must submit an application to the DEA asking for permission to do so.<sup>197</sup> This application must describe “the nature and motive behind the research, the security measures in protecting the human subjects,” and “the substances used in conducting such an inquiry.”<sup>198</sup> “A copy of this application is thereupon sent to the Food & Drug Administration (FDA) for medical evaluation before a final decision is made...”<sup>199</sup> After this application process is completed and the applicant's research protocols

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<sup>194</sup>See Dogwill, supra note 189, at 248-249.

<sup>195</sup>See Segal, supra note 59, at 243.

<sup>196</sup>See March 11, 1999 Statement before Subcomm. on Oversight and Investigations Comm. on Commerce in the U.S. House of Representatives, supra note 191.

<sup>197</sup>See Dogwill, supra note 189, at 249.

<sup>198</sup>Id.

<sup>199</sup>Id.

are approved, the FDA and the DEA review the application so that the DEA Administrator can decide whether or not to approve it.<sup>200</sup> They review the application and decide whether or not to approve it according to a number of factors including:

- “(1) its actual or relative potential for abuse;
- (2) Scientific evidence of its pharmacological effect, if known;
  - (3) The state of current scientific knowledge regarding the drug or other substance;
- (4) Its history and current pattern of abuse;
- (5) The scope, duration, and significance of abuse;
- (6) What, if any, risk there is to the public health;
- (7) Its psychic or physiological dependence liability; and
- (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.”<sup>201</sup>

If the DEA decides that marijuana is safe enough under this criteria to allow for the study of its medicinal attributes, it will consider the possibility of rescheduling marijuana.<sup>202</sup> At this stage, the DEA Administrator still retains ultimate authority to decide whether or not to allow the medical study of marijuana, and he/she is granted wide discretion in this decision under the Controlled Substances Act.<sup>203</sup> Only if the DEA Administrator decides that marijuana should be rescheduled to allow for the study of its medical attributes can someone

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<sup>200</sup>See id.

<sup>202</sup>See Dogwill, supra note 189, at 249.

<sup>203</sup>See id.

seeking to use marijuana therapeutically begin the long process of obtaining the FDA's permission to use or market marijuana therapeutically.

Even if the DEA administrator should decide to allow the rescheduling of marijuana so that its medical potential can be studied, marijuana's journey from status as a Schedule-I substance to status as a legally marketable drug is far from over. As a controlled substance, marijuana must also meet the FDA's requirements for safety and medical effectiveness before it can be marketed for therapeutic use. The 1962 Amendments to the Food, Drug, and Cosmetic Act of 1938 require any entity seeking to develop and market any potentially medically useful pharmacological substance that affects the structure or function of the body in an absence of any disease to obtain the affirmative approval of the Food and Drug Administration prior to any such marketing.<sup>204</sup> Moreover, This three-stage application process often takes many years, and begins for the substance's sponsor long before it ever actually presents a formal application to the FDA requesting the right to market the substance.

#### STAGE 1---PRECLINICAL INVESTIGATION IN PREPARATION OF THE

##### IND APPLICATION

The first stage of this application process, where the sponsor of the substance compiles preliminary clinical data on a potential drug and prepares a plan of study for presentation to the FDA in the formal request to test it on humans<sup>205</sup>, is known as the preclinical stage. This preclinical research is performed by the sponsor for the potential drug, usually a pharmaceutical company.<sup>206</sup>

Most of the research at the preclinical stage is performed without direct supervision from

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<sup>204</sup>See Batterman, supra note 187, at 197; See also id. at 201.

<sup>205</sup>See id. at 286-287.

<sup>206</sup>See id.

the Food and Drug Administration.<sup>207</sup> However, the FDA demands a lot of information on the nature of the substance being tested as well as the methodological quality of the scientific investigation in making its decision as to whether or not to approve a potential drug for general marketing.<sup>208</sup> These informational demands create de facto requirements for preclinical studies that heavily influence both the type and the direction of the research that takes place even at this early stage.<sup>209</sup>

Preclinical research begins when the sponsor pharmaceutical company comes up with a pharmacological concept.<sup>210</sup> They must have a biological mechanism they are seeking to regulate and/or some sort of chemical lead that they will be able to follow.<sup>211</sup> One or both of these must be important some how to a particular target disease that the sponsor is seeking to combat.<sup>212</sup> Since the process of developing and gaining approval for a new drug can take as many as 12 years and cost as much as 231 million dollars, the sponsor must closely examine the current state of scientific knowledge regarding the target disease and critically evaluate the probability that the research will yield scientific and/or marketing success before deciding whether or not to commit the resources needed to see this application process through to its conclusion.<sup>213</sup> Once a chemical lead or a connection between a target disease and a biological mechanism is established, scientists prepare various chemical compounds that could potentially affect that mechanism and test these compounds in a wide variety of test systems from laboratory animals to subcellular particles.<sup>214</sup> Those chemical compounds which emerge from these tests having

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<sup>207</sup>Report of the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology, 96<sup>th</sup> Cong. (1980), reprinted in **Peter Barton Hutt & Richard A. Merrill, Food and Drug Law** 514 (Peter Barton Hutt & Richard A. Merrill, eds., 2d ed., 1995).

<sup>208</sup>See Batterman, *supra* note 187, at 202.

<sup>209</sup>See Hutt & Merrill, eds., *supra* note 207, at 514.

<sup>210</sup>See *id.*

<sup>211</sup>See *id.*

<sup>212</sup>See *id.*

<sup>213</sup>See *id.*

<sup>214</sup>See *id.*

some potential prophylactic or therapeutic utility are then subjected to a battery of toxicological tests using at least three different species of laboratory animals.<sup>215</sup> These studies are intended to help scientists determine the dosages at which these compounds become lethal.<sup>216</sup> Various pathological studies are also performed on the animals to which the compounds are administered in order to determine the organ toxicity the substance produces in these animals.<sup>217</sup> The estimated effective dosages in a series of animal species models are compared with the estimated lethal dosages in that same species series to arrive at what is known as a therapeutic ratio.<sup>218</sup> Those compounds with satisfactory therapeutic ratios are then considered for clinical study in humans.<sup>219</sup> The testing that has taken place to this point has eliminated many chemical compounds from consideration for testing in humans, and only a few of the hundreds of chemical compounds originally found to have potential will be considered for testing in humans.<sup>220</sup> Those chemical compounds still considered suitable for study in humans must now undergo further toxicological evaluations to determine how animals metabolize and/or excrete the substance.<sup>221</sup> Finally, the substance is prepared in a more stable, bioavailable form.<sup>222</sup>

Once the drug has been prepared, the sponsor must then file a Notice of Claimed Exemption for an Investigational New Drug (hereinafter an IND Application) with the FDA.<sup>223</sup> This is the formal application requesting the permission from the FDA to begin testing the drug on humans.<sup>224</sup> The FDA requires the sponsor to include extensive information about the preclinical testing on their IND Application. Among the information required is information on the substance's chemical

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<sup>215</sup>See Hutt & Merrill, eds., supra note 207 at 514-515.

<sup>216</sup>See id. at 515.

<sup>217</sup>See id.

<sup>218</sup>See id.

<sup>219</sup>See id.

<sup>220</sup>See id.

<sup>221</sup>See id.

<sup>222</sup>See id.

<sup>223</sup>See id.

<sup>224</sup>See id.



formula, the biological source of the substance, and the procedure by which the sponsor manufactures the drug.<sup>225</sup> In addition, the FDA requires information on short-term as well as long-term studies using at least two different species of animals.<sup>226</sup>

In addition to describing the details of the preclinical testing that has taken place prior to the submission of the IND Application, the IND Application must describe the sponsor, the sponsor's plans for investigation, a detailed breakdown of the three phases of investigation under the IND application,<sup>227</sup> and the scientific qualifications of the people that the sponsor has obtained to conduct the studies.<sup>228</sup> Once this information has been compiled and submitted to the FDA, the FDA has 30 days to evaluate the IND Application to determine whether or not they will allow the sponsor to continue their investigation with human trials.<sup>229</sup>

In deciding whether to allow the sponsor to begin human testing, the FDA seeks to assure the safety of the human subjects, evaluate the adequacy of the laboratory-animal studies completed during the preclinical stage, evaluate the merits of the sponsor's research plan, and evaluate the scientific qualifications of the personnel who will be conducting the human trials.<sup>230</sup> If, after 30 days, the FDA has not notified the sponsor that he cannot begin the human studies, the sponsor can begin the second stage of the application process---the three-phase process for human clinical trials required under FDA law.<sup>231</sup> The preclinical phase of this process can take anywhere from one to four years, and must be completed to the satisfaction of the FDA before any testing of humans can begin.<sup>232</sup>

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<sup>225</sup>See Crites-Leoni, supra note 140, at 287.

<sup>226</sup>See id.

<sup>227</sup>See Batterman, supra note 187, at 202.

<sup>228</sup>See Crites-Leoni, supra note 140, at 287.

<sup>229</sup>See Alison Joy Arnold, Developing, Testing, and Marketing an AIDS Vaccine: Legal Concerns For Manufacturers, 139 U.

**Pa. L. Rev.** 1077, 1081 (April, 1991).

<sup>230</sup>See Hutt & Merrill, eds., supra note 207, at 515.

<sup>231</sup>See id.

<sup>232</sup>See id. at 514-515.

## STAGE 2---THE 3-PHASE HUMAN INVESTIGATION PROCESS

The next stage of the process of FDA approval for the marketing of a new drug is where the drug sponsors conduct clinical testing of the drugs on humans under an FDA-mandated three-phase clinical testing scheme.<sup>233</sup> These tests are performed in order to determine how safe the drug is for human consumption as well as how effective the drug is in the treatment of the diseases or disorders that the drug is intended to treat.<sup>234</sup>

Phase I of the FDA-mandated clinical testing system is the first time in the application process that pharmacologists administer the test drug to humans. Even at this stage, however, the FDA requires these pharmacologists to thoroughly review the data collected during the preclinical stage of the process, and to conduct further preclinical investigation if it turns out that informational inadequacies in the IND Application somehow escaped the attention of the FDA.<sup>235</sup> Once the informational inadequacies in the preclinical research are remedied, the human testing can begin.

Generally, the tests administered to humans in this phase serve only a marginal therapeutic purpose, if they serve a therapeutic purpose at all.<sup>236</sup> The primary purpose of human testing in Phase I is to give investigators an initial idea of the nature of possible side effects of the test drug.<sup>237</sup> Consequently, the test drug in Phase I is usually administered to healthy subjects, rather than patients afflicted with the target disorder.<sup>238</sup> Human test subjects in

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<sup>233</sup>See Batterman, *supra* note 187, at 221.

<sup>234</sup>See *id.* at 221-222.

<sup>235</sup>See Hutt & Merrill, eds., *supra* note 207, at 516.

<sup>236</sup>See Arnold, *supra* note 229, at 1081-1082.

<sup>237</sup>See Crites-Leoni, *supra* note 140, at 287.

<sup>238</sup>See Marsha N. Cohen, *Getting New Drugs to People with AIDS: A Public Policy Response to Lansdale*, 18 *Hastings Const. L. Q.* 471, 473 (Spring, 1991).

Phase I studies often include prison inmates or the urban poor.<sup>239</sup> During Phase I testing, investigators gather extensive data regarding absorption, distribution, and excretion rates for the test drug, as well as information on the drug's metabolites.<sup>240</sup> Phase I testers usually begin by administering the test drug at low doses and then gradually increase the dosage amounts and frequencies if the single doses cause no side effects in the test subjects.<sup>241</sup> From this, the judges attempt to determine the potential side effects that could result from increasing the frequency of the dosages and/or amount of each dosage.<sup>242</sup> Throughout Phase I of the human trials, investigators perform many batteries of laboratory tests on the human subjects in order to identify any side effects that the test drug might be causing in the test subjects at different times.<sup>243</sup> These tests, too, are primarily concerned with determining the safety of the drug, and provide little or no information about the test drug's effectiveness.<sup>244</sup> Conclusions about the test drug's effectiveness, however, are not expected during Phase I. Phase I testing primarily focuses on safety, and only if testers find adverse effects caused by the drug that will limit the use of the drug will the human testing be abandoned before Phase II.

The fact that a drug's therapeutic viability survives Phase I of human testing in no way insures that the FDA will approve the drug for general marketing. Phase I studies are usually of a limited scope, involving not more than 20 to 100 human test subjects,<sup>245</sup> and as a result, they usually provide only a preliminary look at the safety of the test drug.<sup>246</sup> Since Phase I involves

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<sup>239</sup>See Crites-Leoni, supra note 140, at 287.

<sup>240</sup>See id.

<sup>241</sup>See Hutt & Merrill, eds., supra note 207, at 516.

<sup>242</sup>See Batterman, supra note 187, at 221.

<sup>243</sup>See Hutt & Merrill, eds., supra note 207, at 516.

<sup>244</sup>See id.

<sup>245</sup>See Cohen, supra note 238, at 473.

<sup>246</sup>See id.

a relatively small number of human test subjects, it is still possible that the drug could produce serious adverse side effects that occur at too low of a frequency to be detected in the small pool of Phase I test subjects.<sup>247</sup> Moreover, because these drugs are rarely tested on medical patients during this phase of testing, Phase I usually provides no more than a preliminary gauge of the drug's effectiveness.<sup>248</sup> Consequently, the FDA requires further human testing in Phases II and III.

If Phase I of the investigation reveals no significant safety concerns, investigators will begin Phase II of the human testing scheme.<sup>249</sup> Phase II is the first time investigators test the test drug using human subjects who suffer from the test drug's target disease or diseases.<sup>250</sup> Although Phase II studies involve more human subjects than did Phase I, the numbers of test subjects are still relatively small compared to the numbers that will be utilized during Phase III. At most, Phase II testing will involve several hundred human subjects.<sup>251</sup> It is not so much the number of human subjects as it is the focus of Phase II investigation that truly distinguishes it from the testing performed in Phase I. Although investigators in Phase II testing, as in Phase I testing, focus somewhat on providing more safety assurances and searching for any short-term side effects the drug might cause, Phase II investigators focus their investigation more on determining the effectiveness of the drug at this stage.<sup>252</sup> Consequently, Phase II studies are highly specialized and tailored to best observe the interactions of the test drug with its target disease.<sup>253</sup>

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<sup>247</sup>See id.

<sup>248</sup>See id.

<sup>249</sup>See Hutt & Merrill, eds., supra note 207, at 516.

<sup>250</sup>See id.

<sup>251</sup>See Cohen, supra note 238, at 473.

<sup>252</sup>See Batterman, supra note 187, at 221.

<sup>253</sup>See Hutt & Merrill, eds., supra note 207, at 516.

Because of the focus on effectiveness in Phase II, Phase II investigators take great care to select human test subjects who are without confounding conditions that could taint the validity of any effectiveness data obtained.<sup>254</sup> Consequently, investigators try to minimize the influence of extraneous factors on patient health improvement so that they can better determine how much of a patient's improvement is actually the result of the drug's effect and how much of that improvement is the result of other factors.<sup>255</sup> They try to avoid selecting test subjects who suffer from medical conditions other than the conditions that the test drug is designed to affect, or subjects who are receiving simultaneous treatments for medical conditions other than the target conditions.<sup>256</sup>

In addition to trying to minimize other affirmative factors such as alternative treatments which might influence the test subject's health, investigators also attempt to distinguish patient improvements resulting from the drug's effect from patient improvements resulting from a phenomenon called the "placebo effect".<sup>257</sup> The "placebo effect" is a term that describes the phenomenon occurring in all medical drug testing where the conditions of a certain number of patient test subjects will appear to improve as a result of any treatment regimen regardless of whether that treatment actually has any medical utility or not.<sup>258</sup> Distinguishing the influence of the "placebo effect" from the influence of the drug is important to investigators in building their case regarding the test drug's effectiveness. Consequently, although no statute or regulation actually require that the investigators use placebo-controlled studies or double-blind studies during Phase II testing, investigators still commonly utilize such studies to obtain data in

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<sup>254</sup>See Cohen, supra note 238, at 473.

<sup>255</sup>See id.

<sup>256</sup>See id.

<sup>257</sup>See id.

<sup>258</sup>See id.

support of their claims of the drug's effectiveness.<sup>259</sup>

In addition to tailoring their Phase II studies to minimize extraneous factors influencing patient health, investigators also tailor Phase II studies to determine more specific information regarding the test drug's safety and effectiveness. Typically, studies in Phase II begin with single dose studies and then gradually increase the amount of each dose and the frequency of dosage consumption.<sup>260</sup> This type of study is used so that the investigators can obtain more specific data on safety and effectiveness such as whether or not the drug has the investigators' desired effect, the optimum dosage level for producing this desired effect, and whether or not the drug produces any side effects that would force patients to limit their use of the drug.<sup>261</sup>

Typically, Phase II testing can take anywhere from several months to two years to complete.<sup>262</sup>

A lack of effectiveness discovered during Phase II usually leads to abandonment of the application process at this stage.<sup>263</sup> However, even if a drug proves effective in the small test pool used in Phase II, more widespread testing is required in Phase III to get a better idea of the drug's effectiveness.<sup>264</sup> Likewise, a lack of adverse effects attributable to the drug even at the Phase II level cannot assure that the drug is safe enough for widespread distribution.<sup>265</sup> Consequently, drugs that prove safe and effective at the Phase II level must still undergo a more extensive series of studies in Phase III.<sup>266</sup>

Phase III studies are constructed much like Phase II studies, except that the population of

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<sup>259</sup>See id.

<sup>260</sup>See Hutt & Merrill, eds., supra note 207, at 516.

<sup>261</sup>See id.

<sup>262</sup>See Cohen, supra note 238, at 474.

<sup>263</sup>See Hutt & Merrill, eds., supra note 207, at 516.

<sup>264</sup>See id.

<sup>265</sup>See id.

<sup>266</sup>See id.

human test subjects is generally much larger.<sup>267</sup> Where Phase II studies rarely utilize a test subject population of more than several hundred, Phase III studies utilize a test subject population of anywhere from several hundred to several thousand people.<sup>268</sup> Like Phase II studies, Phase III studies are conducted with an eye toward gathering additional information on the drug's effectiveness as well as its safety.<sup>269</sup> In addition, investigators seek to establish a risk-benefit ratio for the test drug.<sup>270</sup> Phase III investigators also look to gather more specific information on matters such as dosage levels and schedules that produce the best patient results.<sup>271</sup> Also, like Phase II investigators, Phase III investigators commonly utilize masked, comparative studies comparing the test drug's effectiveness with that of either a placebo or a standard drug if another drug for treating the target disease exists.<sup>272</sup>

A key difference between Phase II studies and Phase III studies is that unlike Phase II studies, Phase III studies are generally conducted in a setting meant to approximate the environment in which the drug's general use would take place more closely than in Phase II. Where Phase II studies are designed to minimize the extraneous factors that might affect a patient's response to the test drug,<sup>273</sup> Phase III investigators conduct both controlled and uncontrolled clinical trials.<sup>274</sup> Phase III studies are not designed so strictly to eliminate outside drug-interactions or outside factor influences. Instead, the investigators simply closely monitor the test subjects in the 'general-use-like' Phase III environment looking for potential adverse patient reactions or interactions of the test drug with other drugs or medications the test subject may have

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<sup>267</sup>See Crites-Leoni, supra note 140, at 287.

<sup>268</sup>See Cohen, supra note 238, at 474.

<sup>269</sup>See id.

<sup>270</sup>See Batterman, supra note 187, at 222.

<sup>271</sup>See Cohen, supra note 238, at 474.

<sup>272</sup>See Hutt & Merrill, eds., supra note 207, at 516.

<sup>273</sup>See Cohen, supra note 238, at 473.

<sup>274</sup>See Batterman, supra note 187, at 222.

taken. Investigators allow a greater number of extraneous factors to influence the effects of the drug on the test subject and monitoring those outside factors, hoping to gain a rough idea of the drug's safety and effectiveness when used in a "real-world setting" approximating the usage conditions that would exist if the drug were approved for general marketing.

Even at this level, investigators may still uncover side effects occurring at low frequencies in test subjects using the drug.<sup>275</sup> However, once a drug's effectiveness is established, discovery of a risk of an adverse side effect will not automatically lead to the abandonment of the application or to the rejection of that application.<sup>276</sup> Instead, ultimate approval or denial of the application at this point is determined by scientists and policymakers who compare the drug's benefits with the level of risk that the drug will produce adverse side effects.<sup>277</sup> Decisionmakers tend to tolerate a higher level of risk from a drug that targets a life-threatening condition than from a drug intended to treat a non-life-threatening condition or a condition for which a safer alternative treatment already exists.<sup>278</sup>

Typically, Phase III can take anywhere from one to three years.<sup>279</sup> At the end of Phase III, the test drug's sponsors compile the data from at least two of these Phase III studies and submit it to the FDA as a formal New Drug Application (hereinafter, NDA).<sup>280</sup> Only after the submission of the NDA does the application process enter the third stage, where the FDA examines the NDA and decides whether or not to approve the drug for general marketing.

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<sup>275</sup>See Cohen, supra note 238, at 474.

<sup>276</sup>See id.

<sup>277</sup>See id.

<sup>278</sup>See id.

<sup>279</sup>See id.

<sup>280</sup>See Hutt & Merrill, eds., supra note 207, at 516.



### STAGE 3---SUBMISSION AND FDA EXAMINATION OF THE NDA

Only 10 percent of all the prospective drugs for which sponsors file an IND still have enough merit to file the formal NDA with the Food and Drug Administration after they are subjected to the rigors of the FDA's mandatory three-phase process of human testing.<sup>281</sup> If a drug's sponsor is fortunate enough to possess one of the few drugs that are worthy of an NDA, that sponsor must file the formal NDA with the FDA so that it can begin the lengthy process of examining the application to determine whether or not the data presents enough evidence of the drug's safety and effectiveness to allow its general marketing.<sup>282</sup> FDA review of an NDA is, like the other phases of the application, a lengthy process that requires a great deal of information. The typical NDA contains anywhere from two to 15 volumes of material that summarizes the study's raw data and up to 200,000 pages of raw data.<sup>283</sup> NDA's are rarely significantly shorter than this because of the high volume of information the FDA requires in making its decision on the NDA. The FDA requires that all information regarding the drug's safety and effectiveness, favorable as well as unfavorable, be included in the NDA.<sup>284</sup> The NDA must also contain detailed information regarding the manufacture of the drug as well as the steps the sponsor will take to assure the drug's quality.<sup>285</sup> The FDA also demands detailed and voluminous information from the sponsor regarding clinical testing in both the preclinical trial stage and the human testing stage of the application process.<sup>286</sup> In evaluating the safety of a drug, for example, the FDA requires all information available on aspects of the drug such as:

‘‘1. The interaction of the drug with body

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<sup>281</sup>See id.

<sup>282</sup>See Arnold, *supra* note 229, at 1082.

<sup>283</sup>See Hutt & Merrill, eds., *supra* note 207, at 519.

<sup>284</sup>See id.

<sup>285</sup>See id.

<sup>286</sup>See id.

processes, including: hormonal, enzymic,  
metabolic, and reproductive processes.

2.

distributed in the body tissues, and  
inactivated or excreted.....

3.

metabolism of the drug by the body.

4.

other drugs or even articles of food or  
drink upon the activity of the drug in  
question.

5.

compares with its activity in man....',<sup>287</sup>

The high volume of information that the FDA must comb through in evaluating the NDA often results in long delays in the rendering of an ultimate decision on the sponsor's NDA. By law, the FDA is supposed to render a ruling on the suitability of the drug for public use within 180 days.<sup>288</sup> However, the FDA can, with the consent of the sponsor, withhold a final ruling on the new drug's

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<sup>288</sup>See Arnold, supra note 229 at 1082.

suitability if it needs more information.<sup>289</sup> Moreover, the time that it takes the FDA to make a decision on an NDA has been increasing steadily.<sup>290</sup> The time that typically elapsed from the time the FDA originally received an NDA to its final approval by the FDA was a little more than a year in 1963.<sup>291</sup> It has doubled to around 28 months since then.<sup>292</sup> The FDA's process of sifting through the volumes of information contained in the NDA can prove as time-consuming as the clinical trials themselves.

In the end, however, no amount of NDA information can ever provide the same amount of information about a drug that general use of that drug would provide.<sup>293</sup> Test pools of several thousand subjects simply won't reveal as much effectiveness information or as many risk factors as will the potential pool of millions of users that would result from the general marketing or use of the drug.<sup>294</sup> In addition, not even Phase III clinical studies can properly duplicate the possible complications that could result from the use of the drug by patients who have been misdiagnosed and actually suffer from some other malady, or the risks associated with the use of the drug by doctors not fully familiar with the proper methods of administering the drug.<sup>295</sup> Essentially, not even the most expensive clinical investigations will eliminate all risk or provide fully conclusive evidence of effectiveness.

Consequently, the FDA will either ultimately approve or reject the FDA based on a comparison

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<sup>289</sup>See Hutt & Merrill, eds., supra note 207, at 519.

<sup>290</sup>See id. at 520.

<sup>291</sup>See id.

<sup>292</sup>See id.

<sup>293</sup>See Hutt & Merrill, eds., supra note 287 at 523.

<sup>294</sup>See id.

<sup>295</sup>See id.

of the espoused benefits of the drug with the risks associated with the drug.<sup>296</sup> If the FDA determines, after a risk-benefit analysis, that it is in the public interest to allow the sponsor to market the drug, then it will do so.<sup>297</sup> No statute or regulation sets forth any specific criteria that the FDA must follow in performing this risk-benefit analysis, and the FDA is allowed a certain degree of subjectivity in its decision-making on this issue.<sup>298</sup> As a result, decisions as to whether a drug is to be approved are often quite controversial.<sup>299</sup> If approval is rendered, general marketing can begin. If the FDA is planning on rejecting a sponsor's NDA, the FDA must allow the drug's sponsor a hearing to determine the drug's safety and effectiveness, the sponsor's ability to consistently manufacture the drug, and whether or not the benefits of the drug outweigh its risks when used properly.<sup>300</sup>

The time and money that a drug's sponsor could potentially have to invest to push an IND Application from the preclinical stage through NDA analysis is tremendous. The whole process could take as long as 12 years and cost as much as 231 million dollars.<sup>301</sup> Since it could take a pharmaceutical company years to recoup the costs of an IND Application even if it is ultimately successful, the FDA's new drug approval process is generally only a realistic option for deep-pocketed corporations that can afford to take the substantial financial risk.<sup>302</sup>

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<sup>296</sup>See Hutt & Merrill, eds., supra note 287 at 522.

<sup>297</sup>See id.

<sup>298</sup>See Arnold, supra note 229, at 1082-1083.

<sup>299</sup>See id.

<sup>300</sup>See Hutt & Merrill, eds., supra note 207, at 520.

<sup>301</sup>See Arnold, supra note 229, at 1083.

<sup>302</sup>See Grinspoon & Bakalar, supra note 1, at 256.

## B. CURRENT OBSTACLES TO THE FEDERAL LEGALIZATION OF

### MEDICINAL MARIJUANA

#### OBSTACLES TO FEDERAL LEGALIZATION OF MEDICINAL

#### MARIJUANA INHERENT IN THE NATURE OF MARIJUANA

Even an improvement in the objectivity of governmental attitudes toward marijuana would by no means guarantee marijuana a free ride from contraband status into status as a legal and prescribable drug. As Section A's description of the FDA's new drug approval procedure illustrates, anyone seeking to sponsor marijuana as a potential prescription drug must work through a number of rather substantial 'marijuana-neutral' obstacles in order to meet the FDA's requirements. Marijuana is not exactly well-suited to skate through the FDA's drug approval procedures. One problem that creates an obstacle to FDA new-drug-approval is the fact that the marijuana plant cannot be patented.<sup>303</sup> While this fact presents no substantive problems in terms of proving marijuana's safety or effectiveness, it nonetheless creates substantial bureaucratic obstacles to conducting the studies necessary to meet the FDA's informational demands for all NDA's. The process of applying for FDA permission to market a new drug is extremely expensive and time-consuming.<sup>304</sup> The application, from the preclinical stage through the FDA's final ruling on the sponsor's NDA, can take up to 12 years to complete and cost the sponsor as much as 231 million dollars.<sup>305</sup> The immense investment of time and money required to obtain approval to

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<sup>303</sup>See id.

<sup>304</sup>See Arnold, supra note 229, at 1083.

<sup>305</sup>See id.

market a new drug severely limits the entities who have the financial ability to sponsor a potential new drug. Moreover, the pharmaceutical companies that usually make these investments will not sponsor a potential drug unless they feel that the drug will be profitable.<sup>306</sup>

The 20-year period during which pharmaceutical companies hold can patent control over the new drug, and can consequently price their newly-approved drug somewhat more ‘‘monopolistically’’, is generally where pharmaceutical companies recoup the expenses they incur during the new drug application process.<sup>307</sup> Since marijuana cannot be patented, however, prospective drug sponsors cannot count on any such 20-year monopoly during which they would normally recoup the costs of the IND Application.<sup>308</sup> Few entities with the financial wherewithal to invest in an IND Application for marijuana are willing to invest in seeking the approval of a drug for which they cannot even obtain a temporary patent monopoly.

Another factor that would undoubtedly complicate the process of obtaining FDA approval for medicinal use of the marijuana plant is the fact that marijuana contains a complex mixture of many different chemicals, as opposed to the typical prospective drug comprised of a few well-defined chemical compounds at most.<sup>309</sup> Moreover, because individual patients smoke marijuana differently, and the complex mixture of chemicals that makes up marijuana varies somewhat from plant to plant, it is more difficult for investigators to control the chemical dosage from test subject to test subject.<sup>310</sup> Since the FDA generally demands assurances that a drug’s sponsor demonstrate how it will assure dosage stability before it will approve an NDA,<sup>311</sup> the marijuana

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<sup>306</sup>See Grinspoon & Bakalar, supra note 1, at 256.

<sup>307</sup>See id.

<sup>308</sup>See id.

<sup>309</sup>See Mark A. R. Kleinman, *Marijuana: Costs of Abuse, Costs of Control* 165-166 (1989).

<sup>310</sup>See id.

<sup>311</sup>See Hutt & Merrill, eds., supra note 207, at 515.

plant's complex and often varied chemical structure would present significant problems to investigators trying to allay the safety concerns that marijuana's dosage inconsistencies would elicit in FDA decision-makers.

Another of marijuana's characteristics that would also likely complicate any marijuana IND Application is the method typically used by patients to take marijuana. Marijuana is typically smoked.<sup>312</sup> Currently, no drug that is introduced into the system by smoking is listed on the pharmacopoeia.<sup>313</sup> Pharmaceutical companies have attempted to circumvent this difficulty by creating a drug containing a synthetic version of THC (one of the active ingredients in marijuana) that could be taken orally,<sup>314</sup> but for many patients, this pill is prohibitively expensive.<sup>315</sup> Moreover, most patients have reported that natural marijuana was more effective in treating their symptoms.<sup>316</sup> Furthermore, since one of marijuana's main espoused therapeutic uses is as a treatment for the nausea associated with other treatments such as cancer chemotherapy and the synthetic pill's effectiveness depends primarily on the patient's ability to keep from vomiting, oral ingestion of a pill has often proved significantly less effective than natural marijuana in achieving marijuana's therapeutic results. The smoking of natural marijuana appears to be the most effective and affordable method of obtaining marijuana's therapeutic benefits. However, this method of drug delivery is not currently approved for any drugs on the pharmacopoeia and could further complicate any IND Application for marijuana.

#### OBSTACLES TO FEDERAL LEGALIZATION OF MEDICINAL

<sup>312</sup>See Grinspoon & Bakalar, supra note 1, at 256.

<sup>313</sup>See id.

<sup>314</sup>See id.

<sup>315</sup>See Bergstrom, supra note 3, at 164.

<sup>316</sup>See Grinspoon & Bakalar, supra note 1, at 256.

## MARIJUANA CREATED BY FEDERAL DRUG ENFORCEMENT OFFICIALS

Although the FDA's pre-market approval demands for expensive and time-consuming safety studies and its requirements that sponsors demonstrate their drug's dosage-stability would undoubtedly present significant "'marijuana-neutral'" institutional obstacles to a marijuana IND Application, those institutional obstacles wouldn't inevitably lead to the rejection of any marijuana IND Application. In the end, after all, the FDA's decision to approve or reject an IND Application is based essentially on a balancing of the drug's potential benefits and the risks associated with its use.<sup>317</sup>

At times the FDA has relaxed its usual procedural requirements for pre-market drug approval when it determines that the potential benefits of a drug are significant enough, or the disease to be treated serious enough, to mandate a more relaxed approval standard. For example, the FDA allowed the AIDS-treatment drug AZT to complete the clinical testing phase in under 2 years instead of forcing it to complete the usual seven-to-ten-year process.<sup>318</sup>

If federal drug enforcement agencies would ever allow the studies that would determine marijuana's effectiveness to be conducted, the seriousness of conditions (such as AIDS wasting syndrome)<sup>319</sup> that marijuana is purported to treat could well lead to a similarly relaxed drug-approval process despite the dosage control and chemical make-up questions that marijuana poses. However, the DEA refuses to accept the anecdotal evidence demonstrating marijuana's safety and medical effectiveness that medical marijuana proponents must currently use in their requests for permission to study marijuana's effects. In addition to refusing to accept the validity of existing medical marijuana

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<sup>317</sup>See Hutt & Merrill, eds., supra note 287, at 522.

<sup>318</sup>See Batterman, supra note 187, at 222.

<sup>319</sup>See Grinspoon & Bakalar, supra note 1, at 21.



studies, the DEA also actively impedes all efforts to perform studies that might provide enough evidence of marijuana's safety or medical utility to meet the DEA's evidentiary requirements for rescheduling. the DEA's active refusal to allow any significant clinical exploration of marijuana's medical utility has kept the question of whether marijuana could meet the FDA's institutional requirements from even coming into play. Thus, despite the "marijuana-neutral" policies of the FDA regarding the study and approval of new drugs, federal drug enforcement agencies continue to ensure that marijuana never becomes an acceptable therapeutic substance by frustrating all efforts to prove it's medical utility through clinical studies.

As they did during the Anslinger era, the drug enforcement agencies of the federal government continue to impede all efforts in the medical community to study the medicinal potential of marijuana so that medical experts never even get the opportunity to judge marijuana's medical utility based on its empirical merits. The "Anslingerian" anti-marijuana symbolism still prevalent in the DEA's policies manifests itself in the DEA's circular policy of refusing to reschedule marijuana because of the lack of empirical studies demonstrating its safety and utility while refusing to allow anyone to conduct such studies because of marijuana's Schedule-I status.

Federal officials have taken to responding to increasing and more persuasive claims of marijuana's therapeutic value by "urging others to investigate its medical potential" so these groups can meet the DEA's safety and effectiveness standards and then "creating obstacles that make the research impossible."<sup>320</sup> It appears that even when the FDA approves the protocol for a study examining the potential medical utility of marijuana, federal drug enforcement agencies

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<sup>320</sup>Id. at 257-8.

take steps to ensure that those conducting the study never obtain the marijuana necessary to complete it.

This sabotage of efforts to study marijuana's medical attributes is well-illustrated in the events immediately following the DEA's fifth and final rejection of a marijuana-rescheduling petition in 1992. In rejecting the rescheduling petition, the then-head of the DEA Richard Bonner advised proponents of marijuana rescheduling that their efforts might be more efficiently spent conducting studies to prove marijuana's medical utility rather than pouring their efforts into political lobbying or litigation.<sup>321</sup> Dr. Don Abrams of the University of California at San Francisco was encouraged by Mr. Bonner's statement, and decided to take his advice.<sup>322</sup>

He set up a study designed in conjunction with and approved by the FDA to compare various dosage-levels of smoked-marijuana to orally-ingested dronabinol capsules in treating AIDS wasting syndrome.<sup>323</sup> However, when he sought to obtain the marijuana necessary to conduct the study, the government denied him this marijuana at every turn. The National Institute of Drug Abuse would not allow him to obtain the marijuana from the government-owned marijuana farm, and the DEA refused to allow him to obtain the marijuana by importation.<sup>324</sup>

The federal government's drug enforcement agencies have feigned objectivity and open-mindedness by claiming that marijuana has no medical utility and basing their rejection of efforts to legalize medicinal marijuana on a lack of well-controlled studies demonstrating marijuana's medical efficacy. However, the true sensibilities of federal drug enforcement agencies are revealed when these agencies use their control over the marijuana supply to ensure that studies

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<sup>321</sup>See id. at 257.

<sup>322</sup>See id.

<sup>323</sup>See id.

<sup>324</sup>See id.

proving marijuana's medical potential can never be conducted.

This recent governmental strategy of impeding all efforts to conduct studies that might contradict the DEA's position on marijuana's medical utility evokes memories of the Anslinger-era politics, where Harry Anslinger based his campaign against marijuana on largely unsubstantiated medical claims about the effects of marijuana and then used his political influence to suppress and impede the propagation of any evidence that might have contradicted his medical claims.<sup>325</sup> The similarities between federal drug enforcement agencies' current suppression of therapeutic claims regarding marijuana and the Anslinger-era regime's suppression of all marijuana-supporting medical studies illustrates the large extent to which "Anslingerian" symbolism continues to dominate the federal government's approach to the medical marijuana issue. Furthermore, they illustrate the large extent to which these "Anslingerian" anti-marijuana sensibilities continue to manifest themselves in federal drug enforcement agencies' consistent and pathological refusal to allow any rational exploration of marijuana's medical potential that might demonstrate that marijuana is anything other than an unequivocal menace.

Federal drug-enforcement agencies justify their resistance to the study of marijuana by arguing that the threat of encouraging illicit marijuana use is too great to allow the medical community to even study marijuana's medical potential.<sup>326</sup> In justifying the termination of the Compassionate IND program in the face of increasing evidence of marijuana's medical utility in 1992, government officials indicated a collective fear that in allowing research on the medical attributes of marijuana they would somehow be contributing to a notion that marijuana-smoking must not be

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<sup>325</sup>See discussion *supra* Chapter 1, Section B.

<sup>326</sup>See Kleinman, *supra* note 309, at 166.

as dangerous as its general illicit status would otherwise indicate.<sup>327</sup> Federal drug enforcement officials argue that allowing the study of medical marijuana would give an implicit stamp of acceptability to marijuana that would lead inevitably to an increase in illicit use.<sup>328</sup> This argument loses much of its persuasiveness, however, upon an examination of other dangerous controlled substances that drug enforcement agencies still allowed to be used medically.

The federal drug enforcement agencies argue that medicinal marijuana availability would encourage illicit use by leading to a “leakage” of medicinal marijuana into the arena of illegal use, and by causing the public to view marijuana in a more positive light than it would in the absence of medical acceptability. An examination of another dangerous drug that currently resides on Schedule II of the Controlled Substances Act, however, casts doubt on this governmental claim. Cocaine is a controlled substance with a history of both illicit use and addiction that has been placed on the Controlled Substance Act’s Schedule II,<sup>329</sup> which allows for medical use but still strictly forbids nonmedical use.<sup>330</sup> However, cocaine’s availability for medical use has not contributed significantly to an increased use or availability of cocaine for illegal purposes, nor has cocaine’s Schedule-II-status caused public attitudes toward its safety or acceptability to significantly change.<sup>331</sup>

The negative symbolism associated with marijuana use that the Federal Bureau of Narcotics propagated and popularized during the 1930’s still impedes the study of medicinal marijuana today. The federal government’s drug enforcement officials employ an argument that medical marijuana would lead inevitably lead to an increase in illicit use to impede efforts to study medical marijuana

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<sup>327</sup>See Grinspoon & Bakalar, *supra* note 1, at 22.

<sup>328</sup>See Kleinman, *supra* note 309, at 166.

<sup>329</sup>See Mathre, ed., *supra* note 131, at 4.

<sup>330</sup>See Kleinman, *supra* note 309, at 164.

<sup>331</sup>See *id.* at 167.

even though their argument is directly undercut by both the fact that cocaine is dangerous but available for medical use and the fact that cocaine's medical availability has not led to an increase in its illegal use. This type of inconsistent logic and self-contradiction by drug enforcement officials with respect to the medical marijuana issue indicates that the years have still not significantly dulled the influence of "Anslingerian" anti-marijuana sensibilities on current medical marijuana policies. More specifically, it indicates that federal drug enforcement officials are no more prepared to separate recreational marijuana use from medical marijuana use or rationally examine the therapeutic potential of marijuana today than Harry Anslinger was in the early 1940's when he engineered the suppression of any marijuana studies that reflected marijuana's medical utility to protect America from the recreational menace.

## CONCLUSION

Federal law has made it virtually impossible to legally possess, use, or sell in America since 1937.<sup>332</sup> Since that time, federal drug enforcement agencies have seen to it that little or no substantial research on the effects of marijuana could take place in America. As the preceding chapters have indicated, federal governmental motives for banning marijuana use in 1937 were grounded far more in prejudicial notions that the “decent people” of America needed to be protected from the violent behavior of the socially marginal groups who used marijuana recreationally than any notions that marijuana lacked medical utility.

During the 1930’s and 1940’s, Harry Anslinger and the Federal Bureau of Narcotics waged an anti-marijuana propaganda campaign that associated marijuana so completely with negative images of violent and “doped-up” minorities wreaking havoc on the good citizens of America that when Anslinger began suppressing any studies that suggested that marijuana might have therapeutic potential, even the American Medical Association offered little resistance.<sup>333</sup> After all, fending off the perceived social plague that marijuana threatened to unleash on American society required certain sacrifices. The actions of the officials in the Federal Bureau of Narcotics indicated that they believed (and worked diligently to ensure that the public also believed) that the social threat that recreational marijuana use posed was so substantial that to even allow the consideration of marijuana’s medical potential would pose an unacceptably high risk of encouraging recreational use.

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<sup>332</sup>See Grinspoon & Bakalar, *supra* note 1, at 8.

<sup>333</sup>See discussion *supra* Chapter 1, Section B.

Subsequent evaluation of the propaganda that the FBN used to justify its push for anti-marijuana legislation revealed that most of the propaganda that the FBN used to generate public fear of marijuana “‘was not...based on rational or credible evidence.’”<sup>334</sup> However, the negative imagery with which marijuana became associated during the height of anti-marijuana hysteria in the 1930’s and 1940’s has still continued to dominate the approach that federal drug enforcement agencies have taken in dealing with marijuana from the 1930’s to the present.

Federal drug enforcement agencies continue to demonstrate a complete inability to separate the issue of medical marijuana use from the negative imagery with which marijuana has been associated since the tenure of Harry Anslinger in the FBN. DEA officials continue to refuse to legally recognize any medical potential in marijuana because they fear that an examination of its medical properties would signal an acceptability in marijuana that would lead inevitably to an increase in the social demon of recreational use. They argue this despite the fact they allow other dangerous drugs such as cocaine to be used medically but not recreationally and this has not caused a significant change in public attitudes regarding cocaine or a significant increase in illicit recreational cocaine use.<sup>335</sup>

In the end, however, no amount of contradictory empirical evidence has carried enough weight with federal drug enforcement agencies to elicit any increased willingness to allow marijuana’s therapeutic utility to be explored. When the DEA’s empirical arguments are exhausted, they simply fall back by setting an evidentiary standard of safety and effectiveness that must be met before medical use can begin and then impeding all efforts to gather the evidence necessary to meet that standard. This strategy closely mirrors the strategy (propagating a negative

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<sup>334</sup>Bilz, supra note 5, at 119.

<sup>335</sup>See Kleinman, supra note 309, at 167.

image marijuana and suppressing any studies that contradicted this image) that Harry Anslinger utilized to gain the passage of the first anti-marijuana legislation in 1930's and 1940's. Moreover, it demonstrates that the DEA's approach to dealing with marijuana is just as dominated by the 'Anslingerian' images of marijuana as a chemical pariah today as the FBN was in the 1930's and 1940's.

It is clear that much must be learned about the effects of marijuana before it could ever be approved by the FDA for general medical use. The plant has a complex chemical structure with many active ingredients that interact to produce its effects on the human body.<sup>336</sup> The chemicals, their interaction with each other, and with the human body would undoubtedly need to be studied according to the FDA's new-drug-approval guidelines to determine the nature of the risks they pose and of the therapeutic benefits they offer before general therapeutic use of marijuana could begin.

However, it is also clear that marijuana does possess some degree of therapeutic utility and that the refusal of federal drug enforcement agencies to recognize this fact results more from 'Anslingerian' political concerns about recreational use than from any empirical evidence refuting claims that marijuana possesses medical potential. Given that the original justifications for banning medical marijuana use have been found to be grounded more in political propaganda than in credible evidence, it seems illogical not to reschedule marijuana, so that the facts about marijuana can be separated from the hysterical mythology, and so marijuana's medical potential can be studied. If marijuana

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<sup>336</sup>See id. at 165-166.



were a Schedule-II substance, the FDA would have more authority over determining marijuana's medical utility. At least then the authority to decide the extent of marijuana's medical utility would be based more on empirical medical concerns and a little less on politically-charged "Anslingerian" anti-marijuana politics.

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